

# EXHIBIT A



**TO:** Sabina Downing  
C. R. Bard, Inc.  
730 Central Ave  
Murray Hill, NJ 07974-1199

**RE:** **Process Served in South Carolina**

**FOR:** C. R. Bard, Inc. (Domestic State: NJ)

**Service of Process**

**Transmittal**

01/30/2018

CT Log Number 532709919

**ENCLOSED ARE COPIES OF LEGAL PROCESS RECEIVED BY THE STATUTORY AGENT OF THE ABOVE COMPANY AS FOLLOWS:**

**TITLE OF ACTION:** SHERITA ADAMS, Pltf. vs. C.R. BARD, INC., et al., Dfts.

**DOCUMENT(S) SERVED:** Cover Sheet, Summons, CComplaint

**COURT/AGENCY:** Berkeley County Court of Common Pleas, SC  
Case # 2017CP082285

**NATURE OF ACTION:** The initial ADR conference must be held within 300 days after the filing of the action

**ON WHOM PROCESS WAS SERVED:** CT Corporation System, Columbia, SC

**DATE AND HOUR OF SERVICE:** By Process Server on 01/30/2018 at 15:37

**JURISDICTION SERVED :** South Carolina

**APPEARANCE OR ANSWER DUE:** Within 20 days after service, exclusive of the day of service

**ATTORNEY(S) / SENDER(S):** Lynn Seithel  
Seithel Law LLC  
Post Office Box 1929  
John's Island, SC 29455  
843-557-1699

**ACTION ITEMS:** SOP Papers with Transmittal, via UPS Next Day Air , 1ZX212780108387385  
Image SOP  
Email Notification, Myra McGinley Myra.McGinley@CRBard.com  
Email Notification, Greg Dadika Greg.dadika@crbard.com  
Email Notification, Sabina Downing Sabina.Downing@crbard.com  
Email Notification, Elizabeth Yodice Elizabeth.yodice@crbard.com  
Email Notification, Candace Camarata candace.camarata@crbard.com

**SIGNED:**  
**ADDRESS:** CT Corporation System  
2 Office Park Court  
Suite 103  
Columbia, SC 29223  
804-217-7255

**TELEPHONE:**

STATE OF SOUTH CAROLINA )

COUNTY OF BERKELEY )

SHERITA ADAMS )

Plaintiff(s) )

vs. )

C.R. BARD, INC., and DAVOL, INC., ET AL )

Defendant(s) )

Submitted By: SEITHEL LAW, LLC: LYNN SEITHEL, ESQ. )

Address: P.O. Box 1929  
JOHN'S ISLAND, SC 29457 )

## IN THE COURT OF COMMON PLEAS

## CIVIL ACTION COVERSHEET

2017-CP - \_\_\_\_\_

2017-CP-08-2085

*RG*  
*1/30*  
*2/3/17*

NOTE: The coversheet and information contained herein neither replaces nor supplements the filing and service of pleadings or other papers as required by law. This form is required for the use of the Clerk of Court for the purpose of docketing. It must be filled out completely, signed, and dated. A copy of this coversheet must be served on the defendant(s) along with the Summons and Complaint.

## DOCKETING INFORMATION (Check all that apply)

*\*If Action is Judgment/Settlement do not complete*

JURY TRIAL demanded in complaint.  NON-JURY TRIAL demanded in complaint.  
 This case is subject to ARBITRATION pursuant to the Court Annexed Alternative Dispute Resolution Rules.  
 This case is subject to MEDIATION pursuant to the Court Annexed Alternative Dispute Resolution Rules.  
 This case is exempt from ADR. (Proof of ADR/Exemption Attached)

## NATURE OF ACTION (Check One Box Below)

Contracts  
 Constructions (100)  
 Debt Collection (110)  
 General (130)  
 Breach of Contract (140)  
 Fraud/Bad Faith (150)  
 Failure to Deliver/Warranty (160)  
 Employment Discrim (170)  
 Employment (180)  
 Other (199) \_\_\_\_\_

Torts - Professional Malpractice  
 Dental Malpractice (200)  
 Legal Malpractice (210)  
 Medical Malpractice (220)  
 Previous Notice of Intent Case #  
 Notice/ File Med Mal (230)  
 Other (299) \_\_\_\_\_

Torts - Personal Injury  
 Conversion (310)  
 Motor Vehicle Accident (320)  
 Premises Liability (330)  
 Products Liability (340)  
 Personal Injury (350)  
 Wrongful Death (360)  
 Assault/Battery (370)  
 Slander/Libel (380)  
 Other (399) Survival

Real Property  
 Claim & Delivery (400)  
 Condemnation (410)  
 Foreclosure (420)  
 Mechanic's Lien (430)  
 Partition (440)  
 Possession (450)  
 Building Code Violation (460)  
 Other (499) \_\_\_\_\_

Inmate Petitions  
 PCR (500)  
 Mandamus (520)  
 Habeas Corpus (530)  
 Other (599) \_\_\_\_\_

Administrative Law/Relief  
 Reinstate Drv. License (800)  
 Judicial Review (810)  
 Relief (820)  
 Permanent Injunction (830)  
 Forfeiture-Petition (840)  
 Forfeiture—Consent Order (850)  
 Other (899) \_\_\_\_\_

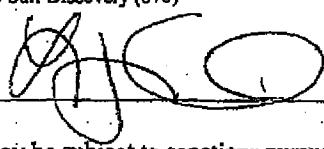
Judgments/ Settlements  
 Death Settlement (700)  
 Foreign Judgment (710)  
 Magistrate's Judgment (720)  
 Minor Settlement (730)  
 Transcript Judgment (740)  
 Lis Pendens (750)  
 Transfer of Structured Settlement Payment Rights Application (760)  
 Confession of Judgment (770)

Appeals  
 Arbitration (900)  
 Magistrate-Civil (910)  
 Magistrate-Criminal (920)  
 Municipal (930)  
 Probate Court (940)  
 SCDOT (950)  
 Worker's Comp (960)  
 Zoning Board (970)  
 Public Service Comm. (990)  
 Employment Security Comm (991)  
 Other (999) \_\_\_\_\_

Special/Complex /Other  
 Environmental (600)  
 Automobile Arb. (610)  
 Medical (620)  
 Other (699) \_\_\_\_\_  
 Sexual Predator (510)  
 Permanent Restraining Order (680)

Pharmaceuticals (630)  
 Unfair Trade Practices (640)  
 Out-of State Depositions (650)  
 Motion to Quash Subpoena in an Out-of-County Action (660)  
 Pre-Suit Discovery (670)

Petition for Workers Compensation Settlement Approval (780)  
 Other (799) \_\_\_\_\_

Submitting Party Signature: 

Date: 10/06/17

Note: Frivolous civil proceedings may be subject to sanctions pursuant to SCRCP, Rule 11, and the South Carolina Frivolous Civil Proceedings Sanctions Act, S.C. Code Ann. §15-36-10 et. seq.

**Effective January 1, 2016, Alternative Dispute Resolution (ADR) is mandatory in all counties, pursuant to Supreme Court Order dated November 12, 2015.**

**SUPREME COURT RULES REQUIRE THE SUBMISSION OF ALL CIVIL CASES TO AN ALTERNATIVE DISPUTE RESOLUTION PROCESS, UNLESS OTHERWISE EXEMPT.**

**Pursuant to the ADR Rules, you are required to take the following action(s):**

1. The parties shall select a neutral and file a "Proof of ADR" form on or by the 210<sup>th</sup> day of the filing of this action. If the parties have not selected a neutral within 210 days, the Clerk of Court shall then appoint a primary and secondary mediator from the current roster on a rotating basis from among those mediators agreeing to accept cases in the county in which the action has been filed.
2. The initial ADR conference must be held within 300 days after the filing of the action.
3. Pre-suit medical malpractice mediations required by S.C. Code §15-79-125 shall be held not later than 120 days after all defendants are served with the "Notice of Intent to File Suit" or as the court directs.
4. Cases are exempt from ADR only upon the following grounds:
  - a. Special proceeding, or actions seeking extraordinary relief such as mandamus, habeas corpus, or prohibition;
  - b. Requests for temporary relief;
  - c. Appeals
  - d. Post Conviction relief matters;
  - e. Contempt of Court proceedings;
  - f. Forfeiture proceedings brought by governmental entities;
  - g. Mortgage foreclosures; and
  - h. Cases that have been previously subjected to an ADR conference, unless otherwise required by Rule 3 or by statute.
5. In cases not subject to ADR, the Chief Judge for Administrative Purposes, upon the motion of the court or of any party, may order a case to mediation.
6. Motion of a party to be exempt from payment of neutral fees due to indigency should be filed with the Court within ten (10) days after the ADR conference has been concluded.

**Please Note:** You must comply with the Supreme Court Rules regarding ADR.  
Failure to do so may affect your case or may result in sanctions.

STATE OF SOUTH CAROLINA )  
COUNTY OF BERKELEY )  
SHERITA ADAMS )  
Plaintiff, )  
vs. )  
C.R. BARD, INC., and DAVOL, INC., )  
and JOHN DOE Sales Representative 1-5, )  
and JANE DOE Sales Representatives )  
Defendants.

IN THE COURT OF COMMON PLEAS  
FOR THE NINTH JUDICIAL CIRCUIT

Case No.: 2017-CP-08-2285

**SUMMONS**

(Jury Trial Demanded)

101 OCT - 6 PM 2:26  
MARY P. BROWN  
CLERK OF COURT  
BERKELEY COUNTY, SC

**TO THE ABOVE NAMED DEFENDANTS:**

YOU ARE HEREBY SUMMONED and required to answer the complaint herein, a copy of which is herewith served upon you, and to serve a copy of your answer to this complaint upon counsel for the Plaintiff at Seithel Law, LLC, Post Office Box 1929, John's Island, SC 29457, within thirty (30) days after service hereof, exclusive of the day of such service, and if you fail to answer the complaint, judgment by default will be rendered against you for the relief demanded in the complaint.

SEITHEL LAW, LLC

By: \_\_\_\_\_

Lynn Seithel (S.C. Bar No. 0069728)  
Post Office Box 1929  
John's Island, SC 29455  
843-557-1699 (direct dial)  
800-818-0433 (fax)  
[lynn@seithellaw.com](mailto:lynn@seithellaw.com) (email)

Charleston, South Carolina

October 6, 2017

STATE OF SOUTH CAROLINA  
COUNTY OF BERKELEY

SHERITA ADAMS

Plaintiff,  
v.

C.R. BARD, INC., and DAVOL, INC., and JOHN  
DOE Sales Representatives 1-5, and JANE DOE  
Sales Representatives

Defendants.

IN THE COURT OF COMMON PLEAS  
FOR THE NINTH JUDICIAL CIRCUIT

Case No.:

2017-CP-08-2085

*184*  
**PLAINTIFF'S COMPLAINT**

**JURY TRIAL REQUESTED**

BERKELEY  
F. BROWN  
JUDGE  
COURT  
OF  
BERKELEY  
COUNTY, SC

PH 2:26

**PLAINTIFF'S COMPLAINT**

COMES NOW Plaintiff Sherita Adams by and through the undersigned attorneys, and for their Complaint against Defendants, states and alleges the following:

1. This is an action for damages suffered by Sherita Adams, "Plaintiff", as a direct and proximate result of Defendants' wrongful conduct in connection with the development, design, manufacture, marketing, distribution and sale of medical device Bard Ventralex Mesh, Lot #HUSB0904 (hereinafter referred to as "Mesh").
2. Plaintiff maintains that the Mesh is defective, dangerous to human health, unfit and unsuitable to be marketed and sold in commerce, and lacked proper warnings and directions as to the dangers associated with its use which were known to Defendants and unknown to Plaintiff at the time of Plaintiff's implant and subsequent complications.

**PARTIES**

3. Plaintiff Sherita Adams, ("Plaintiff"), aged 40, is a resident of Charleston, located in Charleston County, South Carolina.

4. Defendant C.R. Bard, Inc. is a New Jersey based corporation with its manufacturing division headquarters located at 428 Power House Road, Moncks Corner, South Carolina.
5. Defendant Davol, Inc. is a Rhode Island based corporation with its principal place of business at 100 Crossings Boulevard, Warwick, Rhode Island, 02886. Upon information and belief that Davol, Inc. is a wholly-owned subsidiary of C.R. Bard, Inc.
6. Defendant John Doe 1, upon information and belief is a citizen and resident of Berkeley, Charleston, Lexington or Colleton County, State of South Carolina and was at all relevant times at the time of the actions and/or inactions giving rise to this Complaint and was an actual employee, agent and/or apparent agent of Defendants C.R. Bard, Inc. and/or Davol Inc. acting within the scope of his employment/agency.
7. Defendant John Doe 2, upon information and belief is a citizen and resident of Berkeley, Charleston, Colleton or Lexington County, State of South Carolina and was at all relevant times at the time of the actions and/or inactions giving rise to this Complaint and was an actual employee, agent and/or apparent agent of Defendants C.R. Bard, Inc. and/or Davol Inc. acting within the scope of his employment/agency.
8. Defendant John Doe 3, upon information and belief is a citizen and resident of Berkley, Charleston, Colleton or Lexington County, State of South Carolina and was at all relevant times at the time of the actions and/or inactions giving rise to this Complaint and was an actual employee, agent and/or apparent agent of Defendants C.R. Bard, Inc. and/or Davol Inc. acting within the scope of his employment/agency.
9. Defendant John Doe 4, upon information and belief is a citizen and resident of Berkeley, Charleston, Colleton or Lexington County, State of South Carolina and was at all relevant times at the time of the actions and/or inactions giving rise to this Complaint and was an actual

employee, agent and/or apparent agent of Defendants C.R. Bard, Inc. and/or Davol Inc. acting within the scope of his employment/agency.

10. Defendant John Doe 5, upon information and belief is a citizen and resident of Berkeley, Charleston, Colleton or Lexington County, State of South Carolina and was at all relevant times at the time of the actions and/or inactions giving rise to this Complaint and was an actual employee, agent and/or apparent agent of Defendants C.R. Bard, Inc. and/or Davol Inc. acting within the scope of his employment/agency.
11. Defendant Jane Doe 1, upon information and belief is a citizen and resident of Berkeley, Charleston, Colleton or Lexington County, State of South Carolina and was at all relevant times at the time of the actions and/or inactions giving rise to this Complaint and was an actual employee, agent and/or apparent agent of Defendants C.R. Bard, Inc. and/or Davol Inc. acting within the scope of her employment/agency.
12. Defendant Jane Doe 2, upon information and belief is a citizen and resident of Berkeley, Charleston, Colleton or Lexington County, State of South Carolina and was at all relevant times at the time of the actions and/or inactions giving rise to this Complaint and was an actual employee, agent and/or apparent agent of Defendants C.R. Bard, Inc. and/or Davol Inc. acting within the scope of her employment/agency.
13. Defendant Jane Doe 3, upon information and belief is a citizen and resident of Berkeley, Charleston, Colleton or Lexington County, State of South Carolina and was at all relevant times at the time of the actions and/or inactions giving rise to this Complaint and was an actual employee, agent and/or apparent agent of Defendants C.R. Bard, Inc. and/or Davol Inc. acting within the scope of her employment/agency.
14. Defendant Jane Doe 4, upon information and belief is a citizen and resident of Berkeley, Charleston, Colleton or Lexington County, State of South Carolina and was at all relevant

times at the time of the actions and/or inactions giving rise to this Complaint and was an actual employee, agent and/or apparent agent of Defendants C.R. Bard, Inc. and/or Davol Inc. acting within the scope of her employment/agency.

15. Defendant Jane Doe 5, upon information and belief is a citizen and resident of Berkeley, Charleston, Colleton or Lexington County, State of South Carolina and was at all relevant times at the time of the actions and/or inactions giving rise to this Complaint and was an actual employee, agent and/or apparent agent of Defendants C.R. Bard, Inc. and/or Davol Inc. acting within the scope of her employment/agency.
16. In this Complaint, "Defendants" refers to all named Defendants as well as every agent, apparent agent, parent, subsidiary, predecessor, successor and related entities of which each named Defendant to which these allegations pertain.
17. Defendants are companies and/or individuals which were the researchers and/or designers and/or manufacturers and/or assemblers and/or testers and/or labelers and/or packagers and/or promoters and/or sellers and/or distributors and/or otherwise engaged in placing into the stream of commerce a device that is known as Bard Ventralex Mesh, a polypropylene/ePTFE synthetic prosthesis for laparoscopic hernia repair.
18. Defendants placed the Bard Ventralex Patch Mesh product into the stream of commerce throughout the country including South Carolina.
19. Venue in this action properly lies in Berkeley County as the Defendants' conduct substantial business in this county at 428 Power House Road and are subject to the personal jurisdiction of this county. John and Jane Doe Sales Representative Defendants upon information and belief resided in Berkeley County. Furthermore, Defendants sell, market, manufacture, design and/or distribute the Mesh throughout South Carolina.

**BACKGROUND FACTS AND ALLEGATIONS**

20. Defendants design, manufacture, market, package, label, distribute and sell a medical device known as Bard Ventralex Mesh, a polypropylene/ePTFE synthetic prosthesis for laparoscopic hernia repair, where it is intended or reasonably foreseeable that it would be implanted to treat certain persons like Plaintiff.
21. On or around 6/19/2008, Plaintiff had the Mesh implanted during a hernia surgery.
22. On or around 3/6/2013 Plaintiff underwent additional surgery due to the defective qualities of the Mesh.
23. Due to the Bard Ventralex Patch Mesh implant, between 6/19/2008 and the present, Plaintiff suffered from multiple infections, recurrent hernia requiring multiple emergency room visits and subsequent hospitalizations where surgery was required to remove the Bard mesh and repair the recurrent hernia.
24. Neither Plaintiff, nor Plaintiff's implanting and revising surgeons were aware of the defective nature and qualities of the Mesh upon implant or revision.
25. Plaintiff has and will continue to suffer from serious adverse health consequences due to the complications of the initial mesh implantation.
26. The first mesh used in contemporary hernia surgery was a heavyweight polypropylene mesh that was invented in the 1960's and has remained virtually unchanged since then.
27. Defendants' mesh product came on the market and was advertised as a safe, efficient and effective solution for hernia repair having over twelve years of clinical success in minimizing tissue attachment.
28. Defendants marketed the Mesh as being lighter than other brands and the soft, compliant nature made it easy to handle and insert laparoscopic.

29. Defendants marketed the Mesh as a proven effective method that eliminated the need for permanent transfixated sutures.
30. Defendants' mesh product was marketed as producing reproducible results with bragging rights of award-winning innovative design that streamlines laparoscopic procedures that save time and reduce procedure variability and reduce patient trauma.
31. Over the past several years, several meshes like the Mesh used in Plaintiff have been recalled by the FDA.
32. The Defendants and the FDA investigated counterfeit polypropylene surgical mesh labeled with genuine Bard lot numbers and instituted a recall.
33. The counterfeit product was identified primarily to be lots of Bard Flat Mesh also known as Marlex mesh. To date, only four product sizes were identified and were distributed between October 21, 2008 and October 27, 2009.
34. On or around October 6, 2014, the FDA released a safety communication about complications with surgical mesh like the Mesh used to repair the Plaintiff's hernia. "FDA has received reports of complications associated with the Mesh. The complications include adverse reactions to the Mesh, adhesions (when the loops of the intestines adhere to each other or the Mesh), and injuries to nearby organs, nerves or blood vessels. Other complications of hernia repair can occur with or without the Mesh, including infection, chronic grown and hernia recurrence. Most of the complications reported to us so far have been associated with mesh products that have been recalled and are no longer on the market. For information on the recalled Mesh Products, please visit the FDA website...."

35. On or around April 4, 2017, the FDA posted a Hernia Surgical Mesh Implant update on its website where it "described hernias, the different treatment option to repair hernias and recommendations for patients that are considering surgery for their hernias."
36. On the April 4, 2017 FDA Hernia Surgical Mesh website, the FDA reported its findings based upon the review of medical device adverse event reports and of peer-reviewed, scientific literature.
37. On the April 4, 2017 FDA Hernia Surgical Mesh website, the FDA advised that "Many complications related to hernia repair with surgical mesh that have been reported to the FDA have been associated with recalled mesh products that are no longer on the market. Pain, infection, recurrence, adhesion, obstruction and perforation are the most common complications associated with recalled mesh. In the FDA's analysis of medical adverse event reports to the FDA, recalled mesh products were the main cause of bowel perforation and obstruction complications."
38. Plaintiff's injuries previously unknown to be caused by the Mesh implant product in and of itself, were confirmed after the FDA communications that the Plaintiff's injuries were potentially due to the design and or manufacturing defects associated with Plaintiff's Bard mesh implant.
39. As alleged in this complaint, Plaintiff was unable to discover the cause of action against the Defendants due to the misrepresentations and concealments of the Defendants
40. Without compromised sterility, when implanted, this heavyweight mesh is truly a foreign body and causes an inflammatory response which increases due to the high resistance.
41. The Mesh's rupture-threshold is, at a minimum, seven times the strength necessary to protect against the normal occurring injury and its pores are much smaller than would be

deemed appropriate. These characteristics exacerbate the development of inflammatory responses that form with the introduction of a foreign body. When the foreign body is introduced and the inflammation becomes increasingly worse, the polypropylene mesh shrinks and becomes rigid and sharp.

42. The characteristics of this type of mesh are in contrast of anything physiological.
43. There is no part of the human body that is comparable to this heavyweight mesh.
44. The inflammation caused by the Mesh never goes away.
45. The characteristics of the Mesh were and continue to be known to the Defendants and they create an increased risk of unreasonable and dangerous injuries and side effects that have severe and lasting adverse health consequences.
46. The Mesh Products have numerous defects that create a high risk of unreasonable and dangerous injuries and side effects with severe permanent adverse health consequences.  
These defects include, but are not limited to:
  - a. The material is not inert and therefore reacts to human tissues and/or other naturally occurring human bodily contents adversely affecting patient health;
  - b. The Mesh material harbors infections that adversely affect human tissues and patient health;
  - c. The Mesh can migrate from the location of implantation, adversely affecting tissues and patient health;
  - d. The Mesh material unexpectedly shrinks and contracts;
  - e. The Mesh material abrades tissues adversely affecting patient health;
  - f. The Mesh regularly fails to perform the purpose of the implantation that the patient requires removal of the device and/or repeated treatment and surgery;

- g. Due to the various defects, The Mesh regularly causes significant injury to patients such that the Mesh must be removed and/or replaced, resulting in additional surgery;
- h. The Mesh becomes embedded in human tissue over time such that if it needs to be removed due to its various defects, the removal causes damage to the organs and tissues, adversely affecting patient health;
- i. The Mesh is defective in shape, composition, weight, physical, chemical and mechanical properties and is inappropriately engineered for use in the human body;
- j. The Mesh material is defective in manufacture and design in that it causes adhesions, bowel perforations and bowel obstructions.

47. Because of its numerous defects, the Mesh creates an unreasonable risk of injury and other adverse health consequences for patients.

48. Prior to the time that the Mesh was implanted into Plaintiff, Defendants were aware of numerous defects in the Mesh, including, but not limited to, the defects and unreasonable risks identified with the Mesh.

49. Defendants developed, designed, manufactured, labeled, packaged, distributed, marketed, supplied, advertised, sold and otherwise engaged in all activities that are part and parcel of the sale and distribution of the Mesh with the intent that they would be implanted in patients.

50. Defendants were aware that implanting the Mesh Products in patients was likely to cause injury and harm to the patients, like Plaintiff, into whom the Mesh was implanted.

51. Alternatively, Defendants failed to exercise reasonable care in determining the risks and potential adverse consequences of implanting the Mesh Products into patients.
52. Upon information and belief, Defendants were in control of designing, assembling, manufacturing, marketing, testing, distributing, packaging, labeling, processing, supplying, marketing, advertising, promoting, selling and issuing of Mesh Product warnings and related information with respect to its Mesh Products.
53. Defendants' Mesh product was utilized and implanted into Plaintiff in a manner that was intended or reasonably foreseeable to Defendants.
54. The Mesh implanted into Plaintiff was in the same or substantially similar condition as when they left the possession of Defendants; and in the condition directed by Defendants.
55. Even though Defendants have known or should have known that the Mesh created a foreseeable, unreasonable risks of harm to patients in whom they were implanted, Defendants continued to market and sell the Mesh in the United States, including South Carolina.
56. Defendants failed to provide adequate and accurate warnings and information about the risks that the Mesh causes an unreasonably high rate of harm to patients implanted with the Mesh.
57. Despite the knowledge of the defects associated with the use of polypropylene mesh, Defendants manufactured, marketed and distributed the Mesh with the intent that it would be implanted in patients. Defendants knew that implanting the mesh into patients such as Plaintiff was likely to cause injury and harm.

58. In addition, or in the alternative, Defendants failed to exercise reasonable care in determining the risk and potential adverse consequences of implanting the Mesh into patients such as Plaintiff.
59. Defendants made public statements in the form of written product descriptions, product labels, promotional materials and other sales communications that asserted that implanting the Mesh was safe. These statements were made intending that both medical professionals and the general public would rely on them and that the public would pay for the Mesh and that medical professionals would insert the Mesh into their patients. At the time that the Defendants made these statements they knew or should have known them to be inaccurate.
60. Prior to Plaintiff suffering the injuries described, Defendants were or should have been aware of numerous bodily injuries caused by the Mesh implantation. These injuries include, but are not limited to, an unreasonably high rate of erosion, infection, migration, obstruction, recurrence, extrusion, perforation and chronic pain.
61. The Defendants are global healthcare leaders dedicated to advancing the delivery of Healthcare by creating innovative products and services focusing on Mesh in the Hernia repair.
62. Despite the fact that the Defendants know or should know that the Mesh creates a foreseeable and unreasonable risk of harm to those into whom it is implanted, the Defendants continue to market the Mesh.
63. Defendants have never provided adequate and accurate warnings and information concerning the risks that the Mesh causes an unreasonably high rate of erosion, infection,

extrusion, perforation, recurrence, migration, obstruction, chronic pain and/or abscess to patients implanted with the Mesh.

64. Defendants placed and/or were affiliated with the Mesh being placed into the stream of commerce.
65. Plaintiff was injured by Defendants' mesh.
66. Plaintiff became aware that the Mesh was related to Plaintiff's injuries at some point after the October 6, 2014 Safety Communication from the FDA about Mesh products like the Mesh implanted in Plaintiff.
67. The Mesh was implanted into Plaintiff in the same or in a substantially similar condition as it was when it left possession of Defendants and in the condition and manner which was directed by and expected by the Defendants.

#### CAUSES OF ACTION

##### COUNT I STRICT LIABILITY

68. Plaintiff re-alleges each and every prior allegation in this Complaint.
69. At all relevant times, Defendants were responsible for the design, development, processing, manufacturing, testing, packaging, advertising, promoting, marketing, distributing, labeling and/or selling of the Mesh and placing the Mesh into the stream of commerce.
70. At all relevant times the Mesh was expected to reach, and did reach, consumers in the State of South Carolina and throughout the United States, including Plaintiff and

Plaintiff's physicians, without any substantial change in the condition in which the product was sold.

71. At all relevant times, the Defendants intended for the Mesh to be implanted into members of the general public, including Plaintiff, and knew or should have known that the Mesh would be surgically implanted into members of the general public including Plaintiff.
72. The implantation of Defendant's Mesh into Plaintiff was done in a manner reasonably foreseeable or intended by the Defendants.
73. At all relevant times, Defendants had a duty to the Plaintiff and the Plaintiff's physicians to design, development, process, manufacture, test, package, advertise, promote, market, distribute, label and/or sell the Mesh that is reasonably safe, suitable, and fit for its intended or reasonably foreseeable uses.
74. At all relevant times the Mesh was designed, developed, processed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled and/or sold in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following circumstances:
  - a. When placed in the stream of commerce, Defendants' Mesh contained manufacturing and design defects, which rendered the product unreasonably dangerous for its intended use;
  - b. The Mesh was defectively designed in that the materials used in the design of the mesh were not safe for the placement into the human body without the substantial risks of harm to Plaintiff and Plaintiff's organs;

- c. The label which was designed by Defendants to accompany the Mesh product for use in promotion and sales to the Plaintiff and Plaintiff's Physicians was defective in its design in that it did not accurately, adequately and truthfully disclose the adverse events associated with use of the Mesh and did not accurately, adequately and truthfully disclose the post-marketing events associated with the use of the Mesh and other design defects yet to be determined;
- d. The Mesh's manufacturing and design defects occurred while the Mesh was in the possession and control of Defendants;
- e. The Mesh's manufacturing and design defects existed before the Mesh left the control of the Defendants;
- f. The Mesh was insufficiently tested;
- g. The Mesh causes harmful side effects that outweighed any potential utility;
- h. The Mesh was not accompanied by adequate instructions, and/or adequate accurate warnings to fully appraise consumers, including Plaintiff, of the full nature and extent of the risks and side effects associated with its use; and

75. At the time the Mesh left the control of the Defendants, there were practical, feasible and safer alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the Mesh. These safer alternative designs were economically and technologically feasible and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the Product's utility.

76. The Defendants' Mesh is inherently dangerous and defective, unfit and unsafe for its intended and reasonably foreseeable uses, and does not meet or perform to the expectations of patients and their healthcare providers.
77. The Mesh creates risks to the health and safety of the patients that are far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and that outweigh the utility of the Mesh.
78. Defendants intentionally and recklessly designed, manufactured, marketed, labeled, sold and distributed the Mesh with wanton and willful and/or conscious disregard for the rights and health of Plaintiff and others, and with malice, placing their economic interests above the safety of the Plaintiff and others.
79. As a direct and proximate cause of the Defendants' wrongful conduct, Plaintiff suffered and will continue to suffer severe and permanent personal injuries including but not limited to pain, suffering, disability, impairment, loss of enjoyment of life, as well as economic losses.

**WHEREFORE**, Plaintiff demands judgment against Defendants in a sum in excess of \$75,000, for costs incurred, for attorney's fees, and for such other and further relief as the Court deems equitable, just and proper.

**COUNT II**  
**PRODUCTS LIABILITY FAILURE TO WARN**

80. Plaintiff re-alleges each and every prior allegation in this Complaint.
81. At all relevant times, Defendants were responsible for the design, development, processing, manufacturing, testing, packaging, advertising, promoting, marketing,

distributing, labeling and/or selling of the Mesh and placing the Mesh into the stream of commerce.

82. Defendants have engaged in the business of selling, distributing, supplying, manufacturing, marketing, and/or promoting Mesh and through that conduct have knowingly and intentionally placed Mesh into the stream commerce with full knowledge that it would be surgically implanted in consumers such as Plaintiff.
83. Defendants sold, distributed, supplied, manufactured, and/or promoted the Mesh to Plaintiff and to Plaintiff's Physicians.
84. Defendants expected the Mesh that they sold, distributed, supplied, manufactured and/or promoted to reach – and the Mesh did in fact reach – surgeons and consumers, including Plaintiff and Plaintiff's Physicians, without any substantial change in the condition of the Mesh from when it was initially distributed by Defendants.
85. At all relevant times the Mesh was defective and unsafe in manufacture such that it was unreasonably dangerous to the user, and was so at the time it was distributed and sold by Defendants and implanted into Plaintiff.
86. The defective condition of the Mesh was due in part to the fact that it was not accompanied by adequate and accurate warnings regarding the frequency and potential for adverse events associated with the Mesh such as contraction, migration, perforation of organs, adhesions, injuries to organs, nerves and/or blood vessels, infection, recurrence, and other increased risks of severe life-threatening complications as a result of its use.
87. These defects caused serious injury to Plaintiff, whose surgeons used Mesh in its intended and foreseeable manner.

88. At all relevant times, Defendants had a duty to properly design, manufacture, test, inspect, package, label, distribute, market, examine, maintain supply, provide proper warnings, and take such steps to assure that the Mesh did not cause users to suffer from unreasonable and dangerous side effects.
89. Defendants negligently and recklessly labeled, distributed, and promoted the Mesh and failed to warn that it was dangerous and unsafe for the use and purpose for which it was intended.
90. Defendants negligently and recklessly failed to warn of the nature and scope of the side effects associated with Mesh, described herein in the following manners:
  - a. The warnings and/or instructions that were given by Defendants failed to adequately and accurately warn and instruct users, including Plaintiff and Plaintiff's physicians, of the true risks associated with the Mesh including, but not limited to pain, hardening, contraction, migration, perforation, infection, adhesion, and obstruction from the over-engineered mesh and resulting complications and/or additional surgery; and
  - b. The Mesh was further defective due to inadequate post-marketing warnings, labeling, and/or instructions because, after Defendants knew or should have known of the high risk of serious bodily harm, Defendants failed to provide adequate and accurate warnings to purchasers and ultimate users — including Plaintiff and Plaintiff's physicians — of the true risks associated with its use and the potential to cause serious injury; and
  - c. Defendants were aware of the probable consequences of this alleged conduct.

- 91. Despite the fact that Defendants knew or should have known that the Mesh caused serious injuries, they failed to exercise reasonable care to warn of the dangerous side effects including but not limited to migration, adhesion, obstruction, contraction, recurrence and organ perforation from Mesh, even though these side effects were known or reasonably scientifically knowable at the time of distribution.
- 92. Defendants willfully and deliberately planned to avoid the consequences associated with their failure to warn, and in doing so, Defendants acted with a conscious disregard for the safety of Plaintiff.
- 93. Plaintiff could not have discovered any defect in the Mesh through the exercise of reasonable care.
- 94. Plaintiff reasonably relied upon the skill, superior knowledge, and judgment of Defendants.
- 95. Had Defendants properly disclosed the risks associated with the Mesh, Plaintiff and Plaintiff's Physicians would have avoided the risks and chosen a different product or procedure for Plaintiff's condition prior to the Mesh implant.
- 96. Defendants, as manufacturers and/or distributors of the Mesh are held to the level of knowledge of an expert in the field.
- 97. As a direct and proximate cause of the Defendants' wrongful conduct, Plaintiff suffered and will continue to suffer severe and permanent personal injuries including but not limited to pain, suffering, disability, impairment, loss of enjoyment of life, as well as economic losses.

**WHEREFORE**, Plaintiff demands judgment against Defendants in a sum in excess of \$75,000, for costs incurred, for attorney's fees, and for such other and further relief as the Court deems equitable, just and proper.

**COUNT III**  
**NEGLIGENCE**

98. Plaintiff re-alleges each and every prior allegation in this Complaint.
99. At all relevant times Defendants had a duty to exercise reasonable care in the design, manufacture, marketing, labeling, advertising, supply, promotion, packaging, sale and/or distribution of the Mesh, including a duty to assure that the Mesh did not cause unreasonable, dangerous harm and personal injuries to users.
100. Defendants failed to exercise ordinary care in the design, manufacture, marketing, labeling, advertising, supply, promotion, packaging sale and/or distribution, quality assurance, quality control, and distribution of the Mesh in that Defendants knew or should have known that the Mesh created a high and unreasonable risk of harm and personal injuries.
101. Defendants' negligence included, but was not limited to, the following acts and omissions:
  - a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling and distributing the Mesh without thoroughly and adequately testing it;
  - b. Not conducting sufficient studies and testing to determine whether the Mesh was safe for its intended use(s);

- c. Failing to adequately and accurately warn Plaintiff and Plaintiff's healthcare providers, including the general public and/or the FDA, of the risks associated with its use;
- d. Promoting and recommending the use of the Mesh while suppressing and concealing the known dangers inherent in the use of the Mesh;
- e. Suppressing, concealing, omitting, and/or misrepresenting information to Plaintiff, the medical community and/or the FDA concerning the severity of risks and the dangers inherent in the intended use of the Mesh;
- f. Failing to conduct adequate testing to determine the safety of the Mesh;
- g. Failing to provide a safely manufactured product, to healthcare providers and patients, including Plaintiff; and
- h. Failing to provide sufficient quality control to ensure that its product and genuine lot numbers were not counterfeited.

102. Defendants breached their duty of reasonable care to Plaintiff by defectively designing, manufacturing, placing into the stream of commerce and/or negligently failing to warn of the true nature of the defects associated with the Mesh, which resulted in Plaintiff's injuries and damages.

103. Defendants failed to exercise ordinary and reasonable care in designing, manufacturing, testing, marketing, labeling, packaging, selling and/or distributing Mesh and Defendants negligently failed to provide adequate and adequate warnings and information to Plaintiff and Plaintiff's Physicians.

104. As a direct and proximate cause of the Defendants' wrongful conduct, Plaintiff suffered and will continue to suffer severe and permanent personal injuries including but

not limited to pain, suffering, disability, impairment, loss of enjoyment of life, as well as economic losses.

**WHEREFORE**, Plaintiff demands judgment against Defendants in a sum in excess of \$75,000, for costs incurred, for attorney's fees, and for such other and further relief as the Court deems equitable, just and proper.

**COUNT IV**  
**BREACH OF EXPRESS WARRANTY**

105. Plaintiff re-alleges each and every prior allegation in this Complaint.
106. At all relevant times, Defendants were responsible for the design, development, processing, manufacturing, testing, packaging, advertising, promoting, marketing, distributing, labeling and/or selling of the Mesh and placing the Mesh into the stream of commerce.
107. At all relevant and material times, Defendants manufactured, distributed, marketed, advertised, promoted and sold the Mesh product.
108. At all relevant times Defendants intended that their Mesh be used in the manner that Plaintiff's physician(s) and Plaintiff used the Mesh, and Defendants expressly warranted to Plaintiff and Plaintiff's physicians that the Mesh was safe, effective, and fit, for the intended or foreseeable uses by physicians and ultimate consumers.
109. At all times prior to Plaintiff's implant with the Mesh, Defendants expressly warranted that the Mesh was safe.
110. In the decision to use the Mesh in Plaintiff's hernia repair (s) on or around 6/19/2008, Plaintiff and Plaintiff's physician(s) relied on the skill, judgment,

representations, and express warranties of Defendants. These warranties and representations were false in that the Mesh was not safe and was unfit for the uses for which it was intended.

111. Neither Plaintiff nor Plaintiff's physicians had knowledge of the falsity, inaccuracy or incompleteness of Defendants' representations concerning the mesh when Plaintiff's physician(s) implanted the mesh into the Plaintiff.
112. Plaintiff and Plaintiff's physicians justifiably and detrimentally relied on the warranties and representations of Defendants in the use of the Mesh.
113. Defendants were under a duty to accurately and adequately disclose the defective and unsafe nature of Mesh to physicians and consumers, such as Plaintiff.
114. Defendants had sole access to material facts concerning the defects, and Defendants knew that physicians and users, such as Plaintiff and Plaintiff's physicians, could not have reasonably discovered such defects.
115. By the conduct alleged, Defendants, their agents and employees expressly warranted to Plaintiff and Plaintiff's physicians that the products were merchantable and fit for the purpose intended.
116. This warranty was breached because the Mesh is and was not safe, as Defendants had represented, and Plaintiff was injured as a result of this breach.
117. The Mesh implanted in Plaintiff failed to function as intended and as represented by Defendants because it did not relieve the symptoms or otherwise alleviate the medical problems that it was intended to cure. Instead, the Mesh

caused Plaintiff to suffer serious personal injuries requiring the need for additional future medical treatment and surgery(ies).

118. Accordingly, the Mesh was not fit for the ordinary purpose for which such goods are used and failed to conform to the affirmations and representations of Defendants.

119. Defendants knew that the Mesh was to be used for the particular purpose for which it was used with the Plaintiff and knew that the expertise of Defendants was relied on when the Plaintiff and Plaintiff's physicians made the decision to use the Defendants' Mesh.

120. As a direct and proximate cause of the Defendants' wrongful conduct, Plaintiff suffered and will continue to suffer severe and permanent personal injuries including but not limited to pain, suffering, disability, impairment, loss of enjoyment of life, as well as economic losses.

**WHEREFORE**, Plaintiff demands judgment against Defendants in a sum in excess of \$75,000, for costs incurred, for attorney's fees, and for such other and further relief as the Court deems equitable, just and proper.

**COUNT V**  
**BREACH OF IMPLIED WARRANTY**

121. Plaintiff re-alleges each and every prior allegation in this Complaint.

122. At all relevant times, Defendants were responsible for the design, development, processing, manufacturing, testing, packaging, advertising, promoting, marketing, distributing, labeling and/or selling of the Mesh and placing the Mesh into the stream of commerce.

123. At all relevant and material times, Defendants manufactured, distributed, marketed, advertised, labeled, promoted and sold the Mesh.

124. Prior to the time that the Mesh was used by Plaintiff and Plaintiff's physicians, Defendants impliedly warranted to Plaintiff and/or Plaintiff's physicians that the Mesh was of merchantable quality, was properly manufactured, designed and/or packaged and/or labeled and was safe, effective and fit for the use for which it was intended.

125. Plaintiff and Plaintiff's physicians were and are unskilled in the research, design, and manufacture, labeling and sale of the Mesh and reasonably relied on the skill, judgment and implied warranties of the Defendants, when they made their decisions to purchase and implant the Mesh.

126. The Mesh was not properly manufactured and/or packaged and/or labeled, did not conform to or perform in accordance with design and manufacturing specifications and was not safe or effective neither for its intended, known or foreseeable uses and the mesh was not of merchantable quality, as warranted by Defendants.

127. As a result of the breach of the implied warranties, Plaintiff, after being sold and implanted with Defendants' non-conforming, defective Mesh, suffered injuries and sustained compensable damages.

128. Plaintiff and Plaintiff's physicians reasonably relied upon the skill, superior knowledge, and judgment of the Defendants.

129. As a direct and proximate cause of the Defendants' wrongful conduct, Plaintiff suffered and will continue to suffer severe and permanent personal injuries including but

not limited to pain, suffering, disability, impairment, loss of enjoyment of life, as well as economic losses.

WHEREFORE, Plaintiff demands judgment against Defendants in a sum in excess of \$75,000, for costs incurred, for attorney's fees, and for such other and further relief as the Court deems equitable, just and proper.

**COUNT VI**  
**FRAUD**

130. Plaintiff re-alleges each and every prior allegation in this Complaint.
131. At all relevant times, Defendants were responsible for the design, development, processing, manufacturing, testing, packaging, advertising, promoting, marketing, distributing, labeling and/or selling of the Mesh and placing the Mesh into the stream of commerce.
132. Defendants misrepresented by fraud and/or concealment to Plaintiff, Plaintiff's physicians, and the healthcare industry about the safety and effectiveness of the Mesh and/or fraudulently, intentionally, and/or negligently concealed material information, including adverse information, regarding the safety and effectiveness of Mesh.
133. The alleged misrepresentations and/or active concealments were perpetuated directly and/or indirectly by Defendants.
134. Defendants knew or should have known that these representations were false, and they made the representations with the intent or purpose of deceiving Plaintiff, Plaintiff's physicians, and the healthcare industry.

135. Defendants made these false representations with the intent or purpose that Plaintiff, Plaintiff's physicians, and the healthcare industry would rely on them, leading to the use of Mesh by Plaintiff and Plaintiff's physicians as well as the general public.

136. At all relevant times neither Plaintiff nor Plaintiff's physicians were aware of the falsity, inaccuracy or incompleteness of the statements being made by Defendants and believed them to be true.

137. Had Plaintiff and/or Plaintiff's Physicians been aware of the falsity, inaccuracies and incompleteness of the statements made by the Defendants, Plaintiff nor Plaintiff's physicians would have used the Mesh; Plaintiff would not have been implanted with the Mesh; and Plaintiff would not have suffered severe and life-threatening injuries.

138. Plaintiff, Plaintiff's physicians, and the healthcare industry justifiably relied on and/or were induced by Defendants' misrepresentations and/or active concealment and relied on the absence of information regarding the dangers of Mesh that Defendants suppressed, concealed, and/or failed to disclose to the Plaintiff's detriment.

139. Plaintiff and Plaintiff's physicians justifiably relied, directly or indirectly, on Defendants' misrepresentation and/or active concealment regarding the true dangers of Mesh. Based on the nature of the physician-patient relationship, Defendants had reason to expect that Plaintiff would indirectly rely on Defendants' misrepresentations and/or active concealment.

140. Defendants had a post-sale duty to warn Plaintiff, Plaintiff's physicians, and the general public about the potential risks and complications associated with Mesh in a timely manner.

141. Defendants made the representations and actively concealed information about the defects and dangers of Mesh with the intent and specific desire that Plaintiff and/or Plaintiff's physicians and the consuming public would rely on such information, or the absence of information, in selecting the Mesh as treatment to increase sales and profits.
142. As a result of the concealment and/or suppression of the material facts set forth above, Plaintiff was implanted with the Mesh and suffered the described life threatening and permanent injuries.
143. As a further result of the concealment and/or suppression of the material facts set forth above, Plaintiff was unable discover and/or learn of the causes of action Plaintiff have against the Defendants set forth in this complaint until at least October 6, 2014.
144. As a direct and proximate cause of the Defendants' wrongful conduct, Plaintiff suffered and will continue to suffer severe and permanent personal injuries including but not limited to pain, suffering, disability, impairment, loss of enjoyment of life, as well as economic losses.

**WHEREFORE**, Plaintiff demands judgment against Defendants in a sum in excess of \$75,000, for costs incurred, for attorney's fees, and for such other and further relief as the Court deems equitable, just and proper.

**COUNT VII**  
**CONSTRUCTIVE FRAUD**

145. Plaintiff re-alleges each and every prior allegation in this Complaint.
146. Defendants committed constructive fraud by knowingly making false and material representations with reckless disregard for the truth or falsity of such material

representations and with the intent Plaintiff and Plaintiff's health care professionals and consumers would rely on those material representations.

147. Plaintiff and Plaintiff's health care professionals were unaware of the falsity of Defendant's material representations.

148. Plaintiff was injured as a direct and proximate result of the reliance on Defendants' material representations and/or misrepresentations.

149. Defendants knowingly omitted material information and remained silent despite the fact that they had a duty to inform Plaintiff, Plaintiff's health care professionals and the general public of the inaccuracy of these misrepresentations.

150. These omissions constitute a positive misrepresentation of material fact with the intent that Plaintiff and Plaintiff's health care professionals would rely on Defendant's misrepresentations.

151. Plaintiff and Plaintiff's health care professionals relied on Defendants' misrepresentations.

152. Plaintiff and Plaintiff's health care professionals acted with actual and justifiable reliance on Defendants' representations and Plaintiff was injured as a result.

153. At all relevant times, Defendants had a duty to Plaintiff, Plaintiff's Physicians and the general public to accurately inform them of the risks associated with Mesh and the risk of developing adhesions, perforation, obstruction, recurrence, infection, migration, organ perforation and other life-threatening injuries because Defendants as the suppliers and sellers of the Mesh were in a position of superior knowledge and judgment regarding any potential risks associated with the Mesh.

154. Defendants committed constructive fraud by breaching one or more legal or equitable duties owed to Plaintiff related to the use of Mesh. Their propensity to deceive others is contrary to the public policy of this State and constitutes an injury to public policy.

155. In breaching these duties owed to Plaintiff, Defendants used their position of trust as the suppliers and sellers of the Mesh to increase sales of the medical device at the expense of informing Plaintiff that, by being implanted with the Mesh, he was placing himself at a significantly increased risk of developing life-threatening adhesions, perforations, obstructions, recurrences, infections, migrations, organ perforations, organ failures and other serious injuries.

156. As a direct and proximate cause of the Defendants' wrongful conduct, Plaintiff suffered and will continue to suffer severe and permanent personal injuries including but not limited to pain, suffering, disability, impairment, loss of enjoyment of life, as well as economic losses.

**WHEREFORE**, Plaintiff demands judgment against Defendants in a sum in excess of \$75,000, for costs incurred, for attorney's fees, and for such other and further relief as the Court deems equitable, just and proper.

**COUNT VIII**  
**NEGLIGENT MISREPRESENTATION**

157. Plaintiff re-alleges each and every prior allegation in this Complaint.

158. At all relevant times, Defendants were responsible for the design, development, processing, manufacturing, testing, packaging, advertising, promoting, marketing,

distributing, labeling and/or selling of the Mesh and placing the Mesh into the stream of commerce.

159. Defendants negligently and/or recklessly misrepresented to Plaintiff, Plaintiff's physicians, and the healthcare industry the true characteristics of the safety and effectiveness of Mesh and/or recklessly and/or negligently concealed material information, including accurate adverse information, regarding the safety, effectiveness, and dangers posed by Mesh.

160. Defendants made reckless or negligent misrepresentations and negligently or recklessly concealed information when Defendants knew, or should have known, that Mesh had defects, dangers, and characteristics that were other than what Defendants had represented to Plaintiff, Plaintiff's physician(s) and the healthcare industry generally.

161. These negligent or reckless misrepresentations and/or negligent or reckless failures to disclose were perpetuated directly and/or indirectly by Defendants.

162. Defendants should have known through the exercise of due care that the actions and inactions of the Defendant would lead to the deception of Plaintiff, Plaintiff's physicians, and the healthcare industry.

163. Defendants made these false representations without the exercise of due care knowing that it was reasonable and foreseeable that Plaintiff, Plaintiff's physicians, and the healthcare industry would rely upon these misrepresentations which would lead Plaintiff and Plaintiff's physicians to the use of Mesh in Plaintiff as well as other patients.

164. At all relevant times neither Plaintiff nor Plaintiff's physicians were aware of the falsity, inaccuracy or incompleteness of the statements being made by Defendants and believed the representations of the Defendants about the Mesh to be true. Had they been

aware of the true facts, Plaintiff's physicians would not have implanted the Plaintiff with the Mesh.

165. Plaintiff justifiably relied on and/or was induced by Defendants' negligent or reckless misrepresentations and/or negligent or reckless failures to disclose the dangers of Mesh and relied on the absence of information regarding the dangers of Mesh which Defendants negligently or recklessly suppressed, concealed, or failed to disclose to Plaintiff's detriment.

166. Defendants had a post-sale duty to warn Plaintiff, Plaintiff's physicians, and the general public about the true nature of the potential risks and complications associated with Mesh in a timely manner.

167. Defendants made the representations and actively concealed information about the true nature of the defects and dangers of the Mesh with the absence of due care such that Plaintiff, Plaintiff's Physicians, the healthcare community and the consuming public would rely on such information, or the absence of information, in selecting the Mesh as a treatment.

168. As a result of Defendant's negligent misrepresentation, Plaintiff was implanted with the Mesh and suffered injuries as set forth herein.

169. As a direct and proximate cause of the Defendants' wrongful conduct, Plaintiff suffered and will continue to suffer severe and permanent personal injuries including but not limited to pain, suffering, disability, impairment, loss of enjoyment of life, as well as economic losses.

WHEREFORE, Plaintiff demands judgment against Defendants in a sum in excess of \$75,000, for costs incurred, for attorney's fees, and for such other and further relief as the Court deems equitable, just and proper.

**COUNT IX**  
**UNJUST ENRICHMENT**

170. Plaintiff re-alleges each and every prior allegation in this Complaint.
171. At all relevant times, Defendants were responsible for the design, development, processing, manufacturing, testing, packaging, advertising, promoting, marketing, distributing, labeling and/or selling of the Mesh and placing the Mesh into the stream of commerce.
172. Plaintiff conferred a benefit on Defendants by purchasing the Mesh.
173. Plaintiff, however, did not receive the safe and effective medical device for which Plaintiff paid. It would be inequitable for Defendants to retain this money because Plaintiff did not, in fact, receive a safe and efficacious medical device.
174. By virtue of the conscious wrongdoing alleged herein, Defendants have been unjustly enriched at the expense of Plaintiff who seeks the disgorgement and restitution of Defendants' wrongful profits, revenue and benefits to the extent and in the amount deemed appropriate by the Court and for such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.
175. As a direct and proximate cause of the Defendants' wrongful conduct, Plaintiff suffered and will continue to suffer severe and permanent personal injuries including but not limited to pain, suffering, disability, impairment, loss of enjoyment of life, as well as economic losses.

WHEREFORE, Plaintiff demands judgment against Defendants in a sum in excess of \$75,000, for costs incurred, for attorney's fees, and for such other and further relief as the Court deems equitable, just and proper.

**COUNT X**  
**S.C. UNFAIR TRADE PRACTICES ACT**

176. Plaintiff re-alleges each and every prior allegation in this Complaint.
177. At all relevant times, Defendants were responsible for the design, development, processing, manufacturing, testing, packaging advertising, promoting, marketing, distributing, labeling and/or selling of the Mesh and placing the Mesh into the stream of commerce.
178. As a result of the Defendants' actions and inactions, misrepresentations, representations and concealments related to the Mesh, Plaintiff suffered an ascertainable loss of money.
179. Defendants' actions and inactions, misrepresentations, representations and concealments related to Mesh were unfair deceptive methods and acts under S.C.Ann. §39-5-20.
180. Defendants' actions and inactions, misrepresentations, representations and concealments related to the Mesh were willful and Defendants should have known this conduct was a violation of S.C.Ann. §39-5-20.
181. Defendants' actions and inactions, misrepresentations, representations and concealments related to Mesh were offensive to public policy, immoral, unethical and oppressive.
182. Defendants' actions and inactions, misrepresentations, representations and concealments related to Mesh had the capacity, effect and tendency to deceive.

183. Defendants utilize these same unfair deceptive methods in marketing, distributing and selling Mesh throughout the country and South Carolina and upon information and belief, their actions, inactions, misrepresentations, representations and concealments related to the Mesh have caused Plaintiff as well as other citizens of South Carolina ascertainable losses of money and thus have the potential for repetition.

184. As a direct and proximate cause of Defendants deceptive methods, Plaintiff suffered an ascertainable loss of money.

**WHEREFORE**, Plaintiff demands judgment against Defendants in a sum in excess of \$75,000, for costs incurred, for attorney's fees, and for such other and further relief as the Court deems equitable, just and proper.

**COUNT XI**  
**PUNITIVE DAMAGES**

185. Plaintiff re-alleges each and every prior allegation in this Complaint.

186. At all relevant times, Defendants knew or should have known that Mesh was inherently dangerous with respect to the risks of adhesion, obstruction, recurrence, infection, migration, organ perforation, organ damage and other serious life-threatening injuries.

187. At all relevant times, Defendants attempted to misrepresent and misrepresented the facts concerning the safety and efficacy of Mesh.

188. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety of the Mesh.

189. At all relevant times, Defendants knew and recklessly concealed the true risks posed by the Mesh and its potential to cause adhesions, obstructions, recurrences, infections, migrations, organ perforations, organ damages and other serious life-threatening injuries.

190. Despite their superior knowledge and without adequate and adequate disclosure of the true risks of the Mesh, Defendants continued to aggressively market Mesh to consumers, including Plaintiff.

191. Defendants knew of the lack of adequate, accurate and honest warnings regarding the risk of infection, migration, organ perforation, organ damage and other serious life threatening injuries, but Defendants intentionally concealed and/or recklessly failed to disclose that risk and continued to manufacture, package, label, promote, market, distribute and sell Mesh without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious and/or negligent disregard of the foreseeable harm caused by Mesh.

192. Defendants' intentional and/or reckless failure to disclose information deprived Plaintiff of necessary information to enable Plaintiff and Plaintiff's Physicians to weigh the true risks of using Mesh against its benefits.

193. Had Defendants fulfilled their obligations to health care professionals and consumers, including Plaintiff, by accurately providing the risks and efficacy of the Mesh, Defendants would have lost revenue and market share.

194. Defendants' conduct was committed with knowing, conscious, careless, reckless, willful, wanton and deliberate disregard for the rights and safety of consumers, including

Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

195. As a direct and proximate cause of the Defendants' wrongful conduct, Plaintiff suffered and will continue to suffer severe and permanent personal injuries including but not limited to pain, suffering, disability, impairment, loss of enjoyment of life, as well as economic losses.

**WHEREFORE**, Plaintiff demands judgment against Defendants in a sum in excess of \$75,000, for costs incurred, for attorney's fees, punitive damages and for such other and further relief as the Court deems equitable, just and proper.

**PRAYER FOR RELIEF**

Plaintiff demands judgment against Defendants individually, jointly and severally and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

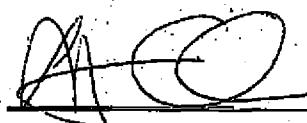
1. For general (non-economic) and special (economic) damages in a sum in excess of the jurisdictional minimum of this Court;
2. For medical, incidental, and hospital expenses according to proof;
3. For pre-judgment and post-judgment interest as provided by law;
4. For full refund of all purchase costs Plaintiff paid for the Mesh;
5. For compensatory damages in excess of the jurisdictional minimum of this Court;
6. For consequential damages in excess of the jurisdictional minimum of this Court;

7. For punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to impress upon Defendants the seriousness of their conduct and to deter similar conduct in the future;
8. For attorneys' fees, expenses, and costs of this action; and
9. For such further relief as this Court deems necessary, just, and proper.

**DEMAND FOR JURY TRIAL**

Plaintiff demands a trial by jury as to all issues.

BY:



Lynn Seithel  
S.C. Bar 69728  
SEITHEL LAW, LLC  
Post Office Box 1929  
Charleston, South Carolina 29457  
(843) 557-1699 direct dial  
(800) 818-0433 (fax)  
[Lynn@SeithelLaw.com](mailto:Lynn@SeithelLaw.com)  
Attorney for Plaintiff

Charleston, South Carolina

Dated: October 6, 2017



**TO:** Sabina Downing  
C. R. Bard, Inc.  
730 Central Ave  
Murray Hill, NJ 07974-1199

**RE:** **Process Served in South Carolina**

**FOR:** Davol Inc. (Domestic State: DE)

**Service of Process**

**Transmittal**

01/30/2018

CT Log Number 532710301

**ENCLOSED ARE COPIES OF LEGAL PROCESS RECEIVED BY THE STATUTORY AGENT OF THE ABOVE COMPANY AS FOLLOWS:**

**TITLE OF ACTION:** Sherita Adams, Ptlf. vs. C.R. Bard, Inc., et al., Dfts. // To: Davol Inc.

**DOCUMENT(S) SERVED:** Cover Sheet, Summons, Complaint

**COURT/AGENCY:** Berkeley County Court of Common Pleas, SC  
Case # 2017CP082285

**NATURE OF ACTION:** Product Liability Litigation - Personal Injury - 04/04/2017

**ON WHOM PROCESS WAS SERVED:** CT Corporation System, Columbia, SC

**DATE AND HOUR OF SERVICE:** By Process Server on 01/30/2018 at 15:37

**JURISDICTION SERVED :** South Carolina

**APPEARANCE OR ANSWER DUE:** Within 30 days after service, exclusive of the day of service

**ATTORNEY(S) / SENDER(S):** Lynn Seithel  
Seithel Law, LLC  
Post Office Box 1929  
Charleston, SC 29457  
843-557-1699

**ACTION ITEMS:** SOP Papers with Transmittal, via UPS Next Day Air , 1ZX212780108387385  
Image SOP  
Email Notification, Sabina Downing Sabina.Downing@crbard.com  
Email Notification, Greg Dadika Greg.dadika@crbard.com  
Email Notification, Myra McGinley Myra.McGinley@CRBard.com  
Email Notification, Elizabeth Yodice Elizabeth.yodice@crbard.com  
Email Notification, Candace Camarata candace.camarata@crbard.com

**SIGNED:**  
**ADDRESS:** CT Corporation System  
2 Office Park Court  
Suite 103  
Columbia, SC 29223

**TELEPHONE:** 804-217-7255

STATE OF SOUTH CAROLINA

COUNTY OF BERKELEY

SHERITA ADAMS

## IN THE COURT OF COMMON PLEAS

## CIVIL ACTION COVERSHEET

Plaintiff(s)

vs.

RL

11/30

C.R. BARD, INC., and DAVOL, INC., ET AL

3:17

Defendant(s)

2017-CP -

2017-CP-08-*DJS*

Submitted By: SEITHEL LAW, LLC; LYNN SEITHEL ESO.

Address: P.O. Box 1929  
JOHN'S ISLAND, SC 29457

SC Bar #: 69728

Telephone #: 843-557-1699

Fax #: 800-818-0433

Other:

E-mail: *lynn@seithellaw.com*

NOTE: The coversheet and information contained herein neither replaces nor supplements the filing and service of pleadings or other papers as required by law. This form is required for the use of the Clerk of Court for the purpose of docketing. It must be filled out completely, signed, and dated. A copy of this coversheet must be served on the defendant(s) along with the Summons and Complaint.

## DOCKETING INFORMATION (Check all that apply)

*\*If Action is Judgment/Settlement do not complete*

JURY TRIAL demanded in complaint.  NON-JURY TRIAL demanded in complaint.

This case is subject to ARBITRATION pursuant to the Court Annexed Alternative Dispute Resolution Rules.

This case is subject to MEDIATION pursuant to the Court Annexed Alternative Dispute Resolution Rules.

This case is exempt from ADR. (Proof of ADR/Exemption Attached)

## NATURE OF ACTION (Check One Box Below)

Contracts

Constructions (100)  
 Debt Collection (110)  
 General (130)  
 Breach of Contract (140)  
 Fraud/Bad Faith (150)  
 Failure to Deliver/Warranty (160)  
 Employment Discrim (170)  
 Employment (180)  
 Other (199) \_\_\_\_\_

Torts - Professional Malpractice

Dental Malpractice (200)  
 Legal Malpractice (210)  
 Medical Malpractice (220)  
 Previous Notice of Intent Case # \_\_\_\_\_  
 Notice/ File Med Mal (230)  
 Other (299) \_\_\_\_\_

Torts - Personal Injury

Conversion (310)  
 Motor Vehicle Accident (320)  
 Premises Liability (330)  
 Products Liability (340)  
 Personal Injury (350)  
 Wrongful Death (360)  
 Assault/Battery (370)  
 Slander/Libel (380)  
 Other (399) Survival

Real Property

Claim & Delivery (400)  
 Condemnation (410)  
 Foreclosure (420)  
 Mechanic's Lien (430)  
 Partition (440)  
 Possession (450)  
 Building Code Violation (460)  
 Other (499) \_\_\_\_\_

Inmate Petitions

PCR (500)  
 Mandamus (520)  
 Habeas Corpus (530)  
 Other (599) \_\_\_\_\_

Administrative Law/Relief

Reinstate Drv. License (800)  
 Judicial Review (810)  
 Relief (820)  
 Permanent Injunction (830)  
 Forfeiture-Petition (840)  
 Forfeiture—Consent Order (850)  
 Other (899) \_\_\_\_\_

Judgments/Settlements

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 Foreign Judgment (710)  
 Magistrate's Judgment (720)  
 Minor Settlement (730)  
 Transcript Judgment (740)  
 Lis Pendens (750)  
 Transfer of Structured Settlement Payment Rights Application (760)  
 Confession of Judgment (770)  
 Petition for Workers Compensation Settlement Approval (780)  
 Other (799) \_\_\_\_\_

Appeals

Arbitration (900)  
 Magistrate-Civil (910)  
 Magistrate-Criminal (920)  
 Municipal (930)  
 Probate Court (940)  
 SCDOT (950)  
 Worker's Comp (960)  
 Zoning Board (970)  
 Public Service Comm. (990)  
 Employment Security Comm (991)  
 Other (999) \_\_\_\_\_

Special/Complex /Other

Environmental (600)  
 Automobile Arb. (610)  
 Medical (620)  
 Other (699) \_\_\_\_\_  
 Sexual Predator (510)  
 Permanent Restraining Order (680)

Pharmaceuticals (630)  
 Unfair Trade Practices (640)  
 Out-of State Depositions (650)  
 Motion to Quash Subpoena in an Out-of-County Action (660)  
 Pre-Suit Discovery (670)

Submitting Party Signature: *[Signature]*

Date: 10/06/17

Note: Frivolous civil proceedings may be subject to sanctions pursuant to SCRCP, Rule 11, and the South Carolina Frivolous Civil Proceedings Sanctions Act, S.C. Code Ann. §15-36-10 et seq.

**Effective January 1, 2016, Alternative Dispute Resolution (ADR) is mandatory in all counties, pursuant to Supreme Court Order dated November 12, 2015.**

**SUPREME COURT RULES REQUIRE THE SUBMISSION OF ALL CIVIL CASES TO AN ALTERNATIVE DISPUTE RESOLUTION PROCESS, UNLESS OTHERWISE EXEMPT.**

**Pursuant to the ADR Rules, you are required to take the following action(s):**

1. The parties shall select a neutral and file a "Proof of ADR" form on or by the 210<sup>th</sup> day of the filing of this action. If the parties have not selected a neutral within 210 days, the Clerk of Court shall then appoint a primary and secondary mediator from the current roster on a rotating basis from among those mediators agreeing to accept cases in the county in which the action has been filed.
2. The initial ADR conference must be held within 300 days after the filing of the action.
3. Pre-suit medical malpractice mediations required by S.C. Code §15-79-125 shall be held not later than 120 days after all defendants are served with the "Notice of Intent to File Suit" or as the court directs.
4. Cases are exempt from ADR only upon the following grounds:
  - a. Special proceeding, or actions seeking extraordinary relief such as mandamus, habeas corpus, or prohibition;
  - b. Requests for temporary relief;
  - c. Appeals
  - d. Post Conviction relief matters;
  - e. Contempt of Court proceedings;
  - f. Forfeiture proceedings brought by governmental entities;
  - g. Mortgage foreclosures; and
  - h. Cases that have been previously subjected to an ADR conference, unless otherwise required by Rule 3 or by statute.
5. In cases not subject to ADR, the Chief Judge for Administrative Purposes, upon the motion of the court or of any party, may order a case to mediation.
6. Motion of a party to be exempt from payment of neutral fees due to indigency should be filed with the Court within ten (10) days after the ADR conference has been concluded.

**Please Note:** You must comply with the Supreme Court Rules regarding ADR.  
Failure to do so may affect your case or may result in sanctions.

STATE OF SOUTH CAROLINA  
COUNTY OF BERKELEY

SHERITA ADAMS

Plaintiff,

vs.

C.R. BARD, INC., and DAVOL, INC.,  
and JOHN DOE Sales Representative 1-5,  
and JANE DOE Sales Representatives

Defendants.

IN THE COURT OF COMMON PLEAS  
FOR THE NINTH JUDICIAL CIRCUIT

Case No.: 2017-CP-08-2285

**SUMMONS**

(Jury Trial Demanded)

10/6/17  
OCT -6 PM 2:26  
MARY F. BROWN  
CLERK OF COURT  
BERKELEY COUNTY, SC

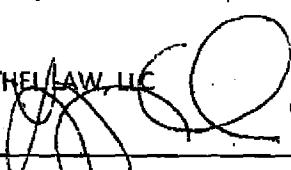
TO THE ABOVE NAMED DEFENDANTS:

YOU ARE HEREBY SUMMONED and required to answer the complaint herein, a copy of which is herewith served upon you, and to serve a copy of your answer to this complaint upon counsel for the Plaintiff at Seithel Law, LLC, Post Office Box 1929, John's Island, SC 29457, within thirty (30) days after service hereof, exclusive of the day of such service, and if you fail to answer the complaint, judgment by default will be rendered against you for the relief demanded in the complaint.

Charleston, South Carolina

October 6, 2017

SEITHEL LAW, LLC

By: 

Lynn Seithel (S.C. Bar No. 0069728)  
Post Office Box 1929  
John's Island, SC 29455  
843-557-1699 (direct dial)  
800-818-0433 (fax)  
[lynn@seithellaw.com](mailto:lynn@seithellaw.com) (email)

STATE OF SOUTH CAROLINA  
COUNTY OF BERKELEY

SHERITA ADAMS

Plaintiff,

v.

C.R. BARD, INC., and DAVOL, INC., and JOHN  
DOE Sales Representatives 1-5, and JANE DOE  
Sales Representatives

Defendants.

IN THE COURT OF COMMON PLEAS  
FOR THE NINTH JUDICIAL CIRCUIT

2017-CP-08-2085

Case No.: 18-17-CP-08-2085

**PLAINTIFF'S COMPLAINT**

**JURY TRIAL REQUESTED**

20 OCT -6  
P. BROWN  
COURT  
CLERK  
CHARLES  
COUNTY, SC  
RECEIVED  
OCT 6 2017  
PM 2:26

**PLAINTIFF'S COMPLAINT**

COMES NOW Plaintiff Sherita Adams by and through the undersigned attorneys, and for their Complaint against Defendants, states and alleges the following:

1. This is an action for damages suffered by Sherita Adams, "Plaintiff", as a direct and proximate result of Defendants' wrongful conduct in connection with the development, design, manufacture, marketing, distribution and sale of medical device Bard Ventralex Mesh, Lot #HUSB0904 (hereinafter referred to as "Mesh").
2. Plaintiff maintains that the Mesh is defective, dangerous to human health, unfit and unsuitable to be marketed and sold in commerce, and lacked proper warnings and directions as to the dangers associated with its use which were known to Defendants and unknown to Plaintiff at the time of Plaintiff's implant and subsequent complications.

**PARTIES**

3. Plaintiff Sherita Adams, ("Plaintiff"), aged 40, is a resident of Charleston, located in Charleston County, South Carolina.

4. Defendant C.R. Bard, Inc. is a New Jersey based corporation with its manufacturing division headquarters located at 428 Power House Road, Moncks Corner, South Carolina.
5. Defendant Davol, Inc. is a Rhode Island based corporation with its principal place of business at 100 Crossings Boulevard, Warwick, Rhode Island, 02886. Upon information and belief that Davol, Inc. is a wholly-owned subsidiary of C.R. Bard, Inc.
6. Defendant John Doe 1, upon information and belief is a citizen and resident of Berkeley, Charleston, Lexington or Colleton County, State of South Carolina and was at all relevant times at the time of the actions and/or inactions giving rise to this Complaint and was an actual employee, agent and/or apparent agent of Defendants C.R. Bard, Inc. and/or Davol Inc. acting within the scope of his employment/agency.
7. Defendant John Doe 2, upon information and belief is a citizen and resident of Berkeley, Charleston, Colleton or Lexington County, State of South Carolina and was at all relevant times at the time of the actions and/or inactions giving rise to this Complaint and was an actual employee, agent and/or apparent agent of Defendants C.R. Bard, Inc. and/or Davol Inc. acting within the scope of his employment/agency.
8. Defendant John Doe 3, upon information and belief is a citizen and resident of Berkeley, Charleston, Colleton or Lexington County, State of South Carolina and was at all relevant times at the time of the actions and/or inactions giving rise to this Complaint and was an actual employee, agent and/or apparent agent of Defendants C.R. Bard, Inc. and/or Davol Inc. acting within the scope of his employment/agency.
9. Defendant John Doe 4, upon information and belief is a citizen and resident of Berkeley, Charleston, Colleton or Lexington County, State of South Carolina and was at all relevant times at the time of the actions and/or inactions giving rise to this Complaint and was an actual

employee, agent and/or apparent agent of Defendants C.R. Bard, Inc. and/or Davol Inc. acting within the scope of his employment/agency.

10. Defendant John Doe 5, upon information and belief is a citizen and resident of Berkeley, Charleston, Colleton or Lexington County, State of South Carolina and was at all relevant times at the time of the actions and/or inactions giving rise to this Complaint and was an actual employee, agent and/or apparent agent of Defendants C.R. Bard, Inc. and/or Davol Inc. acting within the scope of his employment/agency.
11. Defendant Jane Doe 1, upon information and belief is a citizen and resident of Berkeley, Charleston, Colleton or Lexington County, State of South Carolina and was at all relevant times at the time of the actions and/or inactions giving rise to this Complaint and was an actual employee, agent and/or apparent agent of Defendants C.R. Bard, Inc. and/or Davol Inc. acting within the scope of her employment/agency.
12. Defendant Jane Doe 2, upon information and belief is a citizen and resident of Berkeley, Charleston, Colleton or Lexington County, State of South Carolina and was at all relevant times at the time of the actions and/or inactions giving rise to this Complaint and was an actual employee, agent and/or apparent agent of Defendants C.R. Bard, Inc. and/or Davol Inc. acting within the scope of her employment/agency.
13. Defendant Jane Doe 3, upon information and belief is a citizen and resident of Berkeley, Charleston, Colleton or Lexington County, State of South Carolina and was at all relevant times at the time of the actions and/or inactions giving rise to this Complaint and was an actual employee, agent and/or apparent agent of Defendants C.R. Bard, Inc. and/or Davol Inc. acting within the scope of her employment/agency.
14. Defendant Jane Doe 4, upon information and belief is a citizen and resident of Berkeley, Charleston, Colleton or Lexington County, State of South Carolina and was at all relevant

times at the time of the actions and/or inactions giving rise to this Complaint and was an actual employee, agent and/or apparent agent of Defendants C.R. Bard, Inc. and/or Davol Inc. acting within the scope of her employment/agency.

15. Defendant Jane Doe 5, upon information and belief is a citizen and resident of Berkeley, Charleston, Colleton or Lexington County, State of South Carolina and was at all relevant times at the time of the actions and/or inactions giving rise to this Complaint and was an actual employee, agent and/or apparent agent of Defendants C.R. Bard, Inc. and/or Davol Inc. acting within the scope of her employment/agency.
16. In this Complaint, "Defendants" refers to all named Defendants as well as every agent, apparent agent, parent, subsidiary, predecessor, successor and related entities of which each named Defendant to which these allegations pertain.

17. Defendants are companies and/or individuals which were the researchers and/or designers and/or manufacturers and/or assemblers and/or testers and/or labelers and/or packagers and/or promoters and/or sellers and/or distributors and/or otherwise engaged in placing into the stream of commerce a device that is known as Bard Ventralex Mesh, a polypropylene/ePTFE synthetic prosthesis for laparoscopic hernia repair.

18. Defendants placed the Bard Ventralex Patch Mesh product into the stream of commerce throughout the country including South Carolina.

19. Venue in this action properly lies in Berkeley County as the Defendants' conduct substantial business in this county at 428 Power House Road and are subject to the personal jurisdiction of this county. John and Jane Doe Sales Representative Defendants upon information and belief resided in Berkeley County. Furthermore, Defendants sell, market, manufacture, design and/or distribute the Mesh throughout South Carolina.

#### **BACKGROUND FACTS AND ALLEGATIONS**

20. Defendants design, manufacture, market, package, label, distribute and sell a medical device known as Bard Ventralex Mesh, a polypropylene/ePTFE synthetic prosthesis for laparoscopic hernia repair, where it is intended or reasonably foreseeable that it would be implanted to treat certain persons like Plaintiff.
21. On or around 6/19/2008, Plaintiff had the Mesh implanted during a hernia surgery.
22. On or around 3/6/2013 Plaintiff underwent additional surgery due to the defective qualities of the Mesh.
23. Due to the Bard Ventralex Patch Mesh implant, between 6/19/2008 and the present, Plaintiff suffered from multiple infections, recurrent hernia requiring multiple emergency room visits and subsequent hospitalizations where surgery was required to remove the Bard mesh and repair the recurrent hernia.
24. Neither Plaintiff, nor Plaintiff's implanting and revising surgeons were aware of the defective nature and qualities of the Mesh upon implant or revision.
25. Plaintiff has and will continue to suffer from serious adverse health consequences due to the complications of the initial mesh implantation.
26. The first mesh used in contemporary hernia surgery was a heavyweight polypropylene mesh that was invented in the 1960's and has remained virtually unchanged since then.
27. Defendants' mesh product came on the market and was advertised as a safe, efficient and effective solution for hernia repair having over twelve years of clinical success in minimizing tissue attachment.
28. Defendants marketed the Mesh as being lighter than other brands and the soft, compliant nature made it easy to handle and insert laparoscopic.

29. Defendants marketed the Mesh as a proven effective method that eliminated the need for permanent transfixated sutures.
30. Defendants' mesh product was marketed as producing reproducible results with bragging rights of award-winning innovative design that streamlines laparoscopic procedures that save time and reduce procedure variability and reduce patient trauma.
31. Over the past several years, several meshes like the Mesh used in Plaintiff have been recalled by the FDA.
32. The Defendants and the FDA investigated counterfeit polypropylene surgical mesh labeled with genuine Bard lot numbers and instituted a recall.
33. The counterfeit product was identified primarily to be lots of Bard Flat Mesh also known as Marlex/mesh. To date, only four product sizes were identified and were distributed between October 21, 2008 and October 27, 2009.
34. On or around October 6, 2014, the FDA released a safety communication about complications with surgical mesh like the Mesh used to repair the Plaintiff's hernia.  
“FDA has received reports of complications associated with the Mesh. The complications include adverse reactions to the Mesh, adhesions (when the loops of the intestines adhere to each other or the Mesh), and injuries to nearby organs, nerves or blood vessels. Other complications of hernia repair can occur with or without the Mesh, including infection, chronic grown and hernia recurrence. Most of the complications reported to us so far have been associated with mesh products that have been recalled and are no longer on the market. For information on the recalled Mesh Products, please visit the FDA website....”

35. On or around April 4, 2017, the FDA posted a Hernia Surgical Mesh Implant update on its website where it "described hernias, the different treatment option to repair hernias and recommendations for patients that are considering surgery for their hernias."
36. On the April 4, 2017 FDA Hernia Surgical Mesh website, the FDA reported its findings based upon the review of medical device adverse event reports and of peer-reviewed, scientific literature.
37. On the April 4, 2017 FDA Hernia Surgical Mesh website, the FDA advised that "Many complications related to hernia repair with surgical mesh that have been reported to the FDA have been associated with recalled mesh products that are no longer on the market. Pain, infection, recurrence, adhesion, obstruction and perforation are the most common complications associated with recalled mesh. In the FDA's analysis of medical adverse event reports to the FDA, recalled mesh products were the main cause of bowel perforation and obstruction complications."
38. Plaintiff's injuries previously unknown to be caused by the Mesh implant product in and of itself, were confirmed after the FDA communications that the Plaintiff's injuries were potentially due to the design and or manufacturing defects associated with Plaintiff's Bard mesh implant.
39. As alleged in this complaint, Plaintiff was unable to discover the cause of action against the Defendants due to the misrepresentations and concealments of the Defendants
40. Without compromised sterility, when implanted, this heavyweight mesh is truly a foreign body and causes an inflammatory response which increases due to the high resistance.
41. The Mesh's rupture-threshold is, at a minimum, seven times the strength necessary to protect against the normal occurring injury and its pores are much smaller than would be

deemed appropriate. These characteristics exacerbate the development of inflammatory responses that form with the introduction of a foreign body. When the foreign body is introduced and the inflammation becomes increasingly worse, the polypropylene mesh shrinks and becomes rigid and sharp.

42. The characteristics of this type of mesh are in contrast of anything physiological.
43. There is no part of the human body that is comparable to this heavyweight mesh.
44. The inflammation caused by the Mesh never goes away.
45. The characteristics of the Mesh were and continue to be known to the Defendants and they create an increased risk of unreasonable and dangerous injuries and side effects that have severe and lasting adverse health consequences.
46. The Mesh Products have numerous defects that create a high risk of unreasonable and dangerous injuries and side effects with severe permanent adverse health consequences.  
These defects include, but are not limited to:
  - a. The material is not inert and therefore reacts to human tissues and/or other naturally occurring human bodily contents adversely affecting patient health;
  - b. The Mesh material harbors infections that adversely affect human tissues and patient health;
  - c. The Mesh can migrate from the location of implantation, adversely affecting tissues and patient health;
  - d. The Mesh material unexpectedly shrinks and contracts;
  - e. The Mesh material abrades tissues adversely affecting patient health;
  - f. The Mesh regularly fails to perform the purpose of the implantation that the patient requires removal of the device and/or repeated treatment and surgery;

- g. Due to the various defects, The Mesh regularly causes significant injury to patients such that the Mesh must be removed and/or replaced, resulting in additional surgery;
- h. The Mesh becomes embedded in human tissue over time such that if it needs to be removed due to its various defects, the removal causes damage to the organs and tissues, adversely affecting patient health;
- i. The Mesh is defective in shape, composition, weight, physical, chemical and mechanical properties and is inappropriately engineered for use in the human body;
- j. The Mesh material is defective in manufacture and design in that it causes adhesions, bowel perforations and bowel obstructions.

47. Because of its numerous defects, the Mesh creates an unreasonable risk of injury and other adverse health consequences for patients.

48. Prior to the time that the Mesh was implanted into Plaintiff, Defendants were aware of numerous defects in the Mesh, including, but not limited to, the defects and unreasonable risks identified with the Mesh.

49. Defendants developed, designed, manufactured, labeled, packaged, distributed, marketed, supplied, advertised, sold and otherwise engaged in all activities that are part and parcel of the sale and distribution of the Mesh with the intent that they would be implanted in patients.

50. Defendants were aware that implanting the Mesh Products in patients was likely to cause injury and harm to the patients, like Plaintiff, into whom the Mesh was implanted.

51. Alternatively, Defendants failed to exercise reasonable care in determining the risks and potential adverse consequences of implanting the Mesh Products into patients.
52. Upon information and belief, Defendants were in control of designing, assembling, manufacturing, marketing, testing, distributing, packaging, labeling, processing, supplying, marketing, advertising, promoting, selling and issuing of Mesh Product warnings and related information with respect to its Mesh Products.
53. Defendants' Mesh product was utilized and implanted into Plaintiff in a manner that was intended or reasonably foreseeable to Defendants.
54. The Mesh implanted into Plaintiff was in the same or substantially similar condition as when they left the possession of Defendants, and in the condition directed by Defendants.
55. Even though Defendants have known or should have known that the Mesh created a foreseeable, unreasonable risks of harm to patients in whom they were implanted, Defendants continued to market and sell the Mesh in the United States, including South Carolina.
56. Defendants failed to provide adequate and accurate warnings and information about the risks that the Mesh causes an unreasonably high rate of harm to patients implanted with the Mesh.
57. Despite the knowledge of the defects associated with the use of polypropylene mesh, Defendants manufactured, marketed and distributed the Mesh with the intent that it would be implanted in patients. Defendants knew that implanting the mesh into patients such as Plaintiff was likely to cause injury and harm.

58. In addition, or in the alternative, Defendants failed to exercise reasonable care in determining the risk and potential adverse consequences of implanting the Mesh into patients such as Plaintiff.
59. Defendants made public statements in the form of written product descriptions, product labels, promotional materials and other sales communications that asserted that implanting the Mesh was safe. These statements were made intending that both medical professionals and the general public would rely on them and that the public would pay for the Mesh and that medical professionals would insert the Mesh into their patients. At the time that the Defendants made these statements they knew or should have known them to be inaccurate.
60. Prior to Plaintiff suffering the injuries described, Defendants were or should have been aware of numerous bodily injuries caused by the Mesh implantation. These injuries include, but are not limited to, an unreasonably high rate of erosion, infection, migration, obstruction, recurrence, extrusion, perforation and chronic pain.
61. The Defendants are global healthcare leaders dedicated to advancing the delivery of Healthcare by creating innovative products and services focusing on Mesh in the Hernia repair.
62. Despite the fact that the Defendants know or should know that the Mesh creates a foreseeable and unreasonable risk of harm to those into whom it is implanted, the Defendants continue to market the Mesh.
63. Defendants have never provided adequate and accurate warnings and information concerning the risks that the Mesh causes an unreasonably high rate of erosion, infection,

extrusion, perforation, recurrence, migration, obstruction, chronic pain and/or abscess to patients implanted with the Mesh.

64. Defendants placed and/or were affiliated with the Mesh being placed into the stream of commerce.

65. Plaintiff was injured by Defendants' mesh.

66. Plaintiff became aware that the Mesh was related to Plaintiff's injuries at some point after the October 6, 2014 Safety Communication from the FDA about Mesh products like the Mesh implanted in Plaintiff.

67. The Mesh was implanted into Plaintiff in the same or in a substantially similar condition as it was when it left possession of Defendants and in the condition and manner which was directed by and expected by the Defendants.

#### CAUSES OF ACTION

##### COUNT I STRICT LIABILITY

68. Plaintiff re-alleges each and every prior allegation in this Complaint.

69. At all relevant times, Defendants were responsible for the design, development, processing, manufacturing, testing, packaging, advertising, promoting, marketing, distributing, labeling and/or selling of the Mesh and placing the Mesh into the stream of commerce.

70. At all relevant times the Mesh was expected to reach, and did reach, consumers in the State of South Carolina and throughout the United States, including Plaintiff and

Plaintiff's physicians, without any substantial change in the condition in which the product was sold.

71. At all relevant times, the Defendants intended for the Mesh to be implanted into members of the general public, including Plaintiff, and knew or should have known that the Mesh would be surgically implanted into members of the general public including Plaintiff.
72. The implantation of Defendant's Mesh into Plaintiff was done in a manner reasonably foreseeable or intended by the Defendants.
73. At all relevant times, Defendants had a duty to the Plaintiff and the Plaintiff's physicians to design, development, process, manufacture, test, package, advertise, promote, market, distribute, label and/or sell the Mesh that is reasonably safe, suitable, and fit for its intended or reasonably foreseeable uses.
74. At all relevant times the Mesh was designed, developed, processed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled and/or sold in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following circumstances:
  - a. When placed in the stream of commerce, Defendants' Mesh contained manufacturing and design defects, which rendered the product unreasonably dangerous for its intended use;
  - b. The Mesh was defectively designed in that the materials used in the design of the mesh were not safe for the placement into the human body without the substantial risks of harm to Plaintiff and Plaintiff's organs;

- c. The label which was designed by Defendants to accompany the Mesh product for use in promotion and sales to the Plaintiff and Plaintiff's Physicians was defective in its design in that it did not accurately, adequately and truthfully disclose the adverse events associated with use of the Mesh and did not accurately, adequately and truthfully disclose the post-marketing events associated with the use of the Mesh and other design defects yet to be determined;
- d. The Mesh's manufacturing and design defects occurred while the Mesh was in the possession and control of Defendants;
- e. The Mesh's manufacturing and design defects existed before the Mesh left the control of the Defendants;
- f. The Mesh was insufficiently tested;
- g. The Mesh causes harmful side effects that outweighed any potential utility;
- h. The Mesh was not accompanied by adequate instructions, and/or adequate accurate warnings to fully appraise consumers, including Plaintiff, of the full nature and extent of the risks and side effects associated with its use; and

75. At the time the Mesh left the control of the Defendants, there were practical, feasible and safer alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the Mesh. These safer alternative designs were economically and technologically feasible and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the Product's utility.

76. The Defendants' Mesh is inherently dangerous and defective, unfit and unsafe for its intended and reasonably foreseeable uses, and does not meet or perform to the expectations of patients and their healthcare providers.
77. The Mesh creates risks to the health and safety of the patients that are far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and that outweigh the utility of the Mesh.
78. Defendants intentionally and recklessly designed, manufactured, marketed, labeled, sold and distributed the Mesh with wanton and willful and/or conscious disregard for the rights and health of Plaintiff and others, and with malice, placing their economic interests above the safety of the Plaintiff and others.
79. As a direct and proximate cause of the Defendants' wrongful conduct, Plaintiff suffered and will continue to suffer severe and permanent personal injuries including but not limited to pain, suffering, disability, impairment, loss of enjoyment of life, as well as economic losses.

**WHEREFORE**, Plaintiff demands judgment against Defendants in a sum in excess of \$75,000, for costs incurred, for attorney's fees, and for such other and further relief as the Court deems equitable, just and proper.

**COUNT II**  
**PRODUCTS LIABILITY FAILURE TO WARN**

80. Plaintiff re-alleges each and every prior allegation in this Complaint.
81. At all relevant times, Defendants were responsible for the design, development, processing, manufacturing, testing, packaging, advertising, promoting, marketing,

distributing, labeling and/or selling of the Mesh and placing the Mesh into the stream of commerce.

82. Defendants have engaged in the business of selling, distributing, supplying, manufacturing, marketing, and/or promoting Mesh and through that conduct have knowingly and intentionally placed Mesh into the stream commerce with full knowledge that it would be surgically implanted in consumers such as Plaintiff.
83. Defendants sold, distributed, supplied, manufactured, and/or promoted the Mesh to Plaintiff and to Plaintiff's Physicians.
84. Defendants expected the Mesh that they sold, distributed, supplied, manufactured and/or promoted to reach – and the Mesh did in fact reach – surgeons and consumers, including Plaintiff and Plaintiff's Physicians, without any substantial change in the condition of the Mesh from when it was initially distributed by Defendants.
85. At all relevant times the Mesh was defective and unsafe in manufacture such that it was unreasonably dangerous to the user, and was so at the time it was distributed and sold by Defendants and implanted into Plaintiff.
86. The defective condition of the Mesh was due in part to the fact that it was not accompanied by adequate and accurate warnings regarding the frequency and potential for adverse events associated with the Mesh such as contraction, migration, perforation of organs, adhesions, injuries to organs, nerves and/or blood vessels, infection, recurrence and other increased risks of severe life-threatening complications as a result of its use.
87. These defects caused serious injury to Plaintiff, whose surgeons used Mesh in its intended and foreseeable manner.

88. At all relevant times, Defendants had a duty to properly design, manufacture, test, inspect, package, label, distribute, market, examine, maintain supply, provide proper warnings, and take such steps to assure that the Mesh did not cause users to suffer from unreasonable and dangerous side effects.

89. Defendants negligently and recklessly labeled, distributed, and promoted the Mesh and failed to warn that it was dangerous and unsafe for the use and purpose for which it was intended.

90. Defendants negligently and recklessly failed to warn of the nature and scope of the side effects associated with Mesh, described herein in the following manners:

- a. The warnings and/or instructions that were given by Defendants failed to adequately and accurately warn and instruct users, including Plaintiff and Plaintiff's physicians, of the true risks associated with the Mesh including, but not limited to pain, hardening, contraction, migration, perforation, infection, adhesion, and obstruction from the over-engineered mesh and resulting complications and/or additional surgery; and
- b. The Mesh was further defective due to inadequate post-marketing warnings, labeling, and/or instructions because, after Defendants knew or should have known of the high risk of serious bodily harm, Defendants failed to provide adequate and accurate warnings to purchasers and ultimate users -- including Plaintiff and Plaintiff's physicians -- of the true risks associated with its use and the potential to cause serious injury; and
- c. Defendants were aware of the probable consequences of this alleged conduct.

91. Despite the fact that Defendants knew or should have known that the Mesh caused serious injuries, they failed to exercise reasonable care to warn of the dangerous side effects including but not limited to migration, adhesion, obstruction, contraction, recurrence and organ perforation from Mesh, even though these side effects were known or reasonably scientifically knowable at the time of distribution.
92. Defendants willfully and deliberately planned to avoid the consequences associated with their failure to warn, and in doing so, Defendants acted with a conscious disregard for the safety of Plaintiff.
93. Plaintiff could not have discovered any defect in the Mesh through the exercise of reasonable care.
94. Plaintiff reasonably relied upon the skill, superior knowledge, and judgment of Defendants.
95. Had Defendants properly disclosed the risks associated with the Mesh, Plaintiff and Plaintiff's Physicians would have avoided the risks and chosen a different product or procedure for Plaintiff's condition prior to the Mesh implant.
96. Defendants, as manufacturers and/or distributors of the Mesh are held to the level of knowledge of an expert in the field.
97. As a direct and proximate cause of the Defendants' wrongful conduct, Plaintiff suffered and will continue to suffer severe and permanent personal injuries including but not limited to pain, suffering, disability, impairment, loss of enjoyment of life, as well as economic losses.

**WHEREFORE**, Plaintiff demands judgment against Defendants in a sum in excess of \$75,000, for costs incurred, for attorney's fees, and for such other and further relief as the Court deems equitable, just and proper.

**COUNT III**  
**NEGLIGENCE**

98. Plaintiff re-alleges each and every prior allegation in this Complaint.
99. At all relevant times Defendants had a duty to exercise reasonable care in the design, manufacture, marketing, labeling, advertising, supply, promotion, packaging, sale and/or distribution of the Mesh, including a duty to assure that the Mesh did not cause unreasonable, dangerous harm and personal injuries to users.
100. Defendants failed to exercise ordinary care in the design, manufacture, marketing, labeling, advertising, supply, promotion, packaging sale and/or distribution, quality assurance, quality control, and distribution of the Mesh in that Defendants knew or should have known that the Mesh created a high and unreasonable risk of harm and personal injuries.
101. Defendants' negligence included, but was not limited to, the following acts and omissions:
  - a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling and distributing the Mesh without thoroughly and adequately testing it;
  - b. Not conducting sufficient studies and testing to determine whether the Mesh was safe for its intended use(s);

- c. Failing to adequately and accurately warn Plaintiff and Plaintiff's healthcare providers, including the general public and/or the FDA, of the risks associated with its use;
- d. Promoting and recommending the use of the Mesh while suppressing and concealing the known dangers inherent in the use of the Mesh;
- e. Suppressing, concealing, omitting, and/or misrepresenting information to Plaintiff, the medical community and/or the FDA concerning the severity of risks and the dangers inherent in the intended use of the Mesh;
- f. Failing to conduct adequate testing to determine the safety of the Mesh;
- g. Failing to provide a safely manufactured product, to healthcare providers and patients, including Plaintiff; and
- h. Failing to provide sufficient quality control to ensure that its product and genuine lot numbers were not counterfeited.

102. Defendants breached their duty of reasonable care to Plaintiff by defectively designing, manufacturing, placing into the stream of commerce and/or negligently failing to warn of the true nature of the defects associated with the Mesh, which resulted in Plaintiff's injuries and damages.

103. Defendants failed to exercise ordinary and reasonable care in designing, manufacturing, testing, marketing, labeling, packaging, selling and/or distributing Mesh and Defendants negligently failed to provide adequate and adequate warnings and information to Plaintiff and Plaintiff's Physicians.

104. As a direct and proximate cause of the Defendants' wrongful conduct, Plaintiff suffered and will continue to suffer severe and permanent personal injuries including but

not limited to pain, suffering, disability, impairment, loss of enjoyment of life, as well as economic losses.

WHEREFORE, Plaintiff demands judgment against Defendants in a sum in excess of \$75,000, for costs incurred, for attorney's fees, and for such other and further relief as the Court deems equitable, just and proper.

**COUNT IV**  
**BREACH OF EXPRESS WARRANTY**

105. Plaintiff re-alleges each and every prior allegation in this Complaint.
106. At all relevant times, Defendants were responsible for the design, development, processing, manufacturing, testing, packaging, advertising, promoting, marketing, distributing, labeling and/or selling of the Mesh and placing the Mesh into the stream of commerce.
107. At all relevant and material times, Defendants manufactured, distributed, marketed, advertised, promoted and sold the Mesh product.
108. At all relevant times Defendants intended that their Mesh be used in the manner that Plaintiff's physician(s) and Plaintiff used the Mesh, and Defendants expressly warranted to Plaintiff and Plaintiff's physicians that the Mesh was safe, effective, and fit, for the intended or foreseeable uses by physicians and ultimate consumers.
109. At all times prior to Plaintiff's implant with the Mesh, Defendants expressly warranted that the Mesh was safe.
110. In the decision to use the Mesh in Plaintiff's hernia repair (s) on or around 6/19/2008, Plaintiff and Plaintiff's physician(s) relied on the skill, judgment,

representations, and express warranties of Defendants. These warranties and representations were false in that the Mesh was not safe and was unfit for the uses for which it was intended.

111. Neither Plaintiff nor Plaintiff's physicians had knowledge of the falsity, inaccuracy or incompleteness of Defendants' representations concerning the mesh when Plaintiff's physician(s) implanted the mesh into the Plaintiff.
112. Plaintiff and Plaintiff's physicians justifiably and detrimentally relied on the warranties and representations of Defendants in the use of the Mesh.
113. Defendants were under a duty to accurately and adequately disclose the defective and unsafe nature of Mesh to physicians and consumers, such as Plaintiff.
114. Defendants had sole access to material facts concerning the defects, and Defendants knew that physicians and users, such as Plaintiff and Plaintiff's physicians, could not have reasonably discovered such defects.
115. By the conduct alleged, Defendants, their agents and employees expressly warranted to Plaintiff and Plaintiff's physicians that the products were merchantable and fit for the purpose intended.
116. This warranty was breached because the Mesh is and was not safe, as Defendants had represented, and Plaintiff was injured as a result of this breach.
117. The Mesh implanted in Plaintiff failed to function as intended and as represented by Defendants because it did not relieve the symptoms or otherwise alleviate the medical problems that it was intended to cure. Instead, the Mesh

caused Plaintiff to suffer serious personal injuries requiring the need for additional future medical treatment and surgery(ies).

118. Accordingly, the Mesh was not fit for the ordinary purpose for which such goods are used and failed to conform to the affirmations and representations of Defendants.

119. Defendants knew that the Mesh was to be used for the particular purpose for which it was used with the Plaintiff and knew that the expertise of Defendants was relied on when the Plaintiff and Plaintiff's physicians made the decision to use the Defendants' Mesh.

120. As a direct and proximate cause of the Defendants' wrongful conduct, Plaintiff suffered and will continue to suffer severe and permanent personal injuries including but not limited to pain, suffering, disability, impairment, loss of enjoyment of life, as well as economic losses.

WHEREFORE, Plaintiff demands judgment against Defendants in a sum in excess of \$75,000, for costs incurred, for attorney's fees, and for such other and further relief as the Court deems equitable, just and proper.

**COUNT V**  
**BREACH OF IMPLIED WARRANTY**

121. Plaintiff re-alleges each and every prior allegation in this Complaint.

122. At all relevant times, Defendants were responsible for the design, development, processing, manufacturing, testing, packaging, advertising, promoting, marketing, distributing, labeling and/or selling of the Mesh and placing the Mesh into the stream of commerce.

123. At all relevant and material times, Defendants manufactured, distributed, marketed, advertised, labeled, promoted and sold the Mesh.

124. Prior to the time that the Mesh was used by Plaintiff and Plaintiff's physicians, Defendants impliedly warranted to Plaintiff and/or Plaintiff's physicians that the Mesh was of merchantable quality, was properly manufactured, designed and/or packaged and/or labeled and was safe, effective and fit for the use for which it was intended.

125. Plaintiff and Plaintiff's physicians were and are unskilled in the research, design, and manufacture, labeling and sale of the Mesh and reasonably relied on the skill, judgment and implied warranties of the Defendants, when they made their decisions to purchase and implant the Mesh.

126. The Mesh was not properly manufactured and/or packaged and/or labeled, did not conform to or perform in accordance with design and manufacturing specifications and was not safe or effective neither for its intended, known or foreseeable uses and the mesh was not of merchantable quality, as warranted by Defendants.

127. As a result of the breach of the implied warranties, Plaintiff, after being sold and implanted with Defendants' non-conforming, defective Mesh, suffered injuries and sustained compensable damages.

128. Plaintiff and Plaintiff's physicians reasonably relied upon the skill, superior knowledge, and judgment of the Defendants.

129. As a direct and proximate cause of the Defendants' wrongful conduct, Plaintiff suffered and will continue to suffer severe and permanent personal injuries including but

not limited to pain, suffering, disability, impairment, loss of enjoyment of life, as well as economic losses.

**WHEREFORE**, Plaintiff demands judgment against Defendants in a sum in excess of \$75,000, for costs incurred, for attorney's fees, and for such other and further relief as the Court deems equitable, just and proper.

**COUNT VI**  
**FRAUD**

130. Plaintiff re-alleges each and every prior allegation in this Complaint.
131. At all relevant times, Defendants were responsible for the design, development, processing, manufacturing, testing, packaging, advertising, promoting, marketing, distributing, labeling and/or selling of the Mesh and placing the Mesh into the stream of commerce.
132. Defendants misrepresented by fraud and/or concealment to Plaintiff, Plaintiff's physicians, and the healthcare industry about the safety and effectiveness of the Mesh and/or fraudulently, intentionally, and/or negligently concealed material information, including adverse information, regarding the safety and effectiveness of Mesh.
133. The alleged misrepresentations and/or active concealments were perpetuated directly and/or indirectly by Defendants.
134. Defendants knew or should have known that these representations were false, and they made the representations with the intent or purpose of deceiving Plaintiff, Plaintiff's physicians, and the healthcare industry.

135. Defendants made these false representations with the intent or purpose that Plaintiff, Plaintiff's physicians, and the healthcare industry would rely on them, leading to the use of Mesh by Plaintiff and Plaintiff's physicians as well as the general public.

136. At all relevant times neither Plaintiff nor Plaintiff's physicians were aware of the falsity, inaccuracy or incompleteness of the statements being made by Defendants and believed them to be true.

137. Had Plaintiff and/or Plaintiff's Physicians been aware of the falsity, inaccuracies and incompleteness of the statements made by the Defendants, Plaintiff nor Plaintiff's physicians would have used the Mesh; Plaintiff would not have been implanted with the Mesh; and Plaintiff would not have suffered severe and life-threatening injuries.

138. Plaintiff, Plaintiff's physicians, and the healthcare industry justifiably relied on and/or were induced by Defendants' misrepresentations and/or active concealment and relied on the absence of information regarding the dangers of Mesh that Defendants suppressed, concealed, and/or failed to disclose to the Plaintiff's detriment.

139. Plaintiff and Plaintiff's physicians justifiably relied, directly or indirectly, on Defendants' misrepresentation and/or active concealment regarding the true dangers of Mesh. Based on the nature of the physician-patient relationship, Defendants had reason to expect that Plaintiff would indirectly rely on Defendants' misrepresentations and/or active concealment.

140. Defendants had a post-sale duty to warn Plaintiff, Plaintiff's physicians, and the general public about the potential risks and complications associated with Mesh in a timely manner.

141. Defendants made the representations and actively concealed information about the defects and dangers of Mesh with the intent and specific desire that Plaintiff and/or Plaintiff's physicians and the consuming public would rely on such information, or the absence of information, in selecting the Mesh as treatment to increase sales and profits.

142. As a result of the concealment and/or suppression of the material facts set forth above, Plaintiff was implanted with the Mesh and suffered the described life threatening and permanent injuries.

143. As a further result of the concealment and/or suppression of the material facts set forth above, Plaintiff was unable discover and/or learn of the causes of action Plaintiff have against the Defendants set forth in this complaint until at least October 6, 2014.

144. As a direct and proximate cause of the Defendants' wrongful conduct, Plaintiff suffered and will continue to suffer severe and permanent personal injuries including but not limited to pain, suffering, disability, impairment, loss of enjoyment of life, as well as economic losses.

**WHEREFORE**, Plaintiff demands judgment against Defendants in a sum in excess of \$75,000, for costs incurred, for attorney's fees, and for such other and further relief as the Court deems equitable, just and proper.

**COUNT VII**  
**CONSTRUCTIVE FRAUD**

145. Plaintiff re-alleges each and every prior allegation in this Complaint.

146. Defendants committed constructive fraud by knowingly making false and material representations with reckless disregard for the truth or falsity of such material

representations and with the intent Plaintiff and Plaintiff's health care professionals and consumers would rely on those material representations.

147. Plaintiff and Plaintiff's health care professionals were unaware of the falsity of Defendant's material representations.

148. Plaintiff was injured as a direct and proximate result of the reliance on Defendants' material representations and/or misrepresentations.

149. Defendants knowingly omitted material information and remained silent despite the fact that they had a duty to inform Plaintiff, Plaintiff's health care professionals and the general public of the inaccuracy of these misrepresentations.

150. These omissions constitute a positive misrepresentation of material fact with the intent that Plaintiff and Plaintiff's health care professionals would rely on Defendant's misrepresentations.

151. Plaintiff and Plaintiff's health care professionals relied on Defendants' misrepresentations.

152. Plaintiff and Plaintiff's health care professionals acted with actual and justifiable reliance on Defendants' representations and Plaintiff was injured as a result.

153. At all relevant times, Defendants had a duty to Plaintiff, Plaintiff's Physicians and the general public to accurately inform them of the risks associated with Mesh and the risk of developing adhesions, perforation, obstruction, recurrence, infection, migration, organ perforation and other life-threatening injuries because Defendants as the suppliers and sellers of the Mesh were in a position of superior knowledge and judgment regarding any potential risks associated with the Mesh.

154. Defendants committed constructive fraud by breaching one or more legal or equitable duties owed to Plaintiff related to the use of Mesh. Their propensity to deceive others is contrary to the public policy of this State and constitutes an injury to public policy.

155. In breaching these duties owed to Plaintiff, Defendants used their position of trust as the suppliers and sellers of the Mesh to increase sales of the medical device at the expense of informing Plaintiff that, by being implanted with the Mesh, he was placing himself at a significantly increased risk of developing life-threatening adhesions, perforations, obstructions, recurrences, infections, migrations, organ perforations, organ failures and other serious injuries.

156. As a direct and proximate cause of the Defendants' wrongful conduct, Plaintiff suffered and will continue to suffer severe and permanent personal injuries including but not limited to pain, suffering, disability, impairment, loss of enjoyment of life, as well as economic losses.

**WHEREFORE**, Plaintiff demands judgment against Defendants in a sum in excess of \$75,000, for costs incurred, for attorney's fees, and for such other and further relief as the Court deems equitable, just and proper.

**COUNT VIII**  
**NEGLIGENT MISREPRESENTATION**

157. Plaintiff re-alleges each and every prior allegation in this Complaint.

158. At all relevant times, Defendants were responsible for the design, development, processing, manufacturing, testing, packaging, advertising, promoting, marketing,

distributing, labeling and/or selling of the Mesh and placing the Mesh into the stream of commerce.

159. Defendants negligently and/or recklessly misrepresented to Plaintiff, Plaintiff's physicians, and the healthcare industry the true characteristics of the safety and effectiveness of Mesh and/or recklessly and/or negligently concealed material information, including accurate adverse information, regarding the safety, effectiveness, and dangers posed by Mesh.

160. Defendants made reckless or negligent misrepresentations and negligently or recklessly concealed information when Defendants knew, or should have known, that Mesh had defects, dangers, and characteristics that were other than what Defendants had represented to Plaintiff, Plaintiff's physician(s) and the healthcare industry generally.

161. These negligent or reckless misrepresentations and/or negligent or reckless failures to disclose were perpetuated directly and/or indirectly by Defendants.

162. Defendants should have known through the exercise of due care that the actions and inactions of the Defendant would lead to the deception of Plaintiff, Plaintiff's physicians, and the healthcare industry.

163. Defendants made these false representations without the exercise of due care knowing that it was reasonable and foreseeable that Plaintiff, Plaintiff's physicians, and the healthcare industry would rely upon these misrepresentations which would lead Plaintiff and Plaintiff's physicians to the use of Mesh in Plaintiff as well as other patients.

164. At all relevant times neither Plaintiff nor Plaintiff's physicians were aware of the falsity, inaccuracy or incompleteness of the statements being made by Defendants and believed the representations of the Defendants about the Mesh to be true. Had they been

aware of the true facts, Plaintiff's physicians would not have implanted the Plaintiff with the Mesh.

165. Plaintiff justifiably relied on and/or was induced by Defendants' negligent or reckless misrepresentations and/or negligent or reckless failures to disclose the dangers of Mesh and relied on the absence of information regarding the dangers of Mesh which Defendants negligently or recklessly suppressed, concealed, or failed to disclose to Plaintiff's detriment.

166. Defendants had a post-sale duty to warn Plaintiff, Plaintiff's physicians, and the general public about the true nature of the potential risks and complications associated with Mesh in a timely manner.

167. Defendants made the representations and actively concealed information about the true nature of the defects and dangers of the Mesh with the absence of due care such that Plaintiff, Plaintiff's Physicians, the healthcare community and the consuming public would rely on such information, or the absence of information, in selecting the Mesh as a treatment.

168. As a result of Defendant's negligent misrepresentation, Plaintiff was implanted with the Mesh and suffered injuries as set forth herein.

169. As a direct and proximate cause of the Defendants' wrongful conduct, Plaintiff suffered and will continue to suffer severe and permanent personal injuries including but not limited to pain, suffering, disability, impairment, loss of enjoyment of life, as well as economic losses.

**WHEREFORE**, Plaintiff demands judgment against Defendants in a sum in excess of \$75,000, for costs incurred, for attorney's fees, and for such other and further relief as the Court deems equitable, just and proper.

**COUNT IX**  
**UNJUST ENRICHMENT**

170. Plaintiff re-alleges each and every prior allegation in this Complaint.
171. At all relevant times, Defendants were responsible for the design, development, processing, manufacturing, testing, packaging, advertising, promoting, marketing, distributing, labeling and/or selling of the Mesh and placing the Mesh into the stream of commerce.
172. Plaintiff conferred a benefit on Defendants by purchasing the Mesh.
173. Plaintiff, however, did not receive the safe and effective medical device for which Plaintiff paid. It would be inequitable for Defendants to retain this money because Plaintiff did not, in fact, receive a safe and efficacious medical device.
174. By virtue of the conscious wrongdoing alleged herein, Defendants have been unjustly enriched at the expense of Plaintiff who seeks the disgorgement and restitution of Defendants' wrongful profits, revenue and benefits to the extent and in the amount deemed appropriate by the Court and for such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.
175. As a direct and proximate cause of the Defendants' wrongful conduct, Plaintiff suffered and will continue to suffer severe and permanent personal injuries including but not limited to pain, suffering, disability, impairment, loss of enjoyment of life, as well as economic losses.

WHEREFORE, Plaintiff demands judgment against Defendants in a sum in excess of \$75,000, for costs incurred, for attorney's fees, and for such other and further relief as the Court deems equitable, just and proper.

**COUNT X**  
**S.C. UNFAIR TRADE PRACTICES ACT**

176. Plaintiff re-alleges each and every prior allegation in this Complaint.
177. At all relevant times, Defendants were responsible for the design, development, processing, manufacturing, testing, packaging advertising, promoting, marketing, distributing, labeling and/or selling of the Mesh and placing the Mesh into the stream of commerce.
178. As a result of the Defendants' actions and inactions, misrepresentations, representations and concealments related to the Mesh, Plaintiff suffered an ascertainable loss of money.
179. Defendants' actions and inactions, misrepresentations, representations and concealments related to Mesh were unfair deceptive methods and acts under S.C.Ann. §39-5-20.
180. Defendants' actions and inactions, misrepresentations, representations and concealments related to the Mesh were willful and Defendants should have known this conduct was a violation of S.C.Ann. §39-5-20.
181. Defendants' actions and inactions, misrepresentations, representations and concealments related to Mesh were offensive to public policy, immoral, unethical and oppressive.
182. Defendants' actions and inactions, misrepresentations, representations and concealments related to Mesh had the capacity, effect and tendency to deceive.

183. Defendants utilize these same unfair deceptive methods in marketing, distributing and selling Mesh throughout the country and South Carolina and upon information and belief, their actions, inactions, misrepresentations, representations and concealments related to the Mesh have caused Plaintiff as well as other citizens of South Carolina ascertainable losses of money and thus have the potential for repetition.

184. As a direct and proximate cause of Defendants deceptive methods, Plaintiff suffered an ascertainable loss of money.

**WHEREFORE**, Plaintiff demands judgment against Defendants in a sum in excess of \$75,000, for costs incurred, for attorney's fees, and for such other and further relief as the Court deems equitable, just and proper.

**COUNT XI**  
**PUNITIVE DAMAGES**

185. Plaintiff re-alleges each and every prior allegation in this Complaint.

186. At all relevant times, Defendants knew or should have known that Mesh was inherently dangerous with respect to the risks of adhesion, obstruction, recurrence, infection, migration, organ perforation, organ damage and other serious life-threatening injuries.

187. At all relevant times, Defendants attempted to misrepresent and misrepresented the facts concerning the safety and efficacy of Mesh.

188. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety of the Mesh.

189. At all relevant times, Defendants knew and recklessly concealed the true risks posed by the Mesh and its potential to cause adhesions, obstructions, recurrences, infections, migrations, organ perforations, organ damages and other serious life-threatening injuries.

190. Despite their superior knowledge and without adequate and adequate disclosure of the true risks of the Mesh, Defendants continued to aggressively market Mesh to consumers, including Plaintiff.

191. Defendants knew of the lack of adequate, accurate and honest warnings regarding the risk of infection, migration, organ perforation, organ damage and other serious life threatening injuries, but Defendants intentionally concealed and/or recklessly failed to disclose that risk and continued to manufacture, package, label, promote, market, distribute and sell Mesh without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious and/or negligent disregard of the foreseeable harm caused by Mesh.

192. Defendants' intentional and/or reckless failure to disclose information deprived Plaintiff of necessary information to enable Plaintiff and Plaintiff's Physicians to weigh the true risks of using Mesh against its benefits.

193. Had Defendants fulfilled their obligations to health care professionals and consumers, including Plaintiff, by accurately providing the risks and efficacy of the Mesh, Defendants would have lost revenue and market share.

194. Defendants' conduct was committed with knowing, conscious, careless, reckless, willful, wanton and deliberate disregard for the rights and safety of consumers, including

Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

195. As a direct and proximate cause of the Defendants' wrongful conduct, Plaintiff suffered and will continue to suffer severe and permanent personal injuries including but not limited to pain, suffering, disability, impairment, loss of enjoyment of life, as well as economic losses.

**WHEREFORE**, Plaintiff demands judgment against Defendants in a sum in excess of \$75,000, for costs incurred, for attorney's fees, punitive damages and for such other and further relief as the Court deems equitable, just and proper.

**PRAYER FOR RELIEF**

Plaintiff demands judgment against Defendants individually, jointly and severally and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

1. For general (non-economic) and special (economic) damages in a sum in excess of the jurisdictional minimum of this Court;
2. For medical, incidental, and hospital expenses according to proof;
3. For pre-judgment and post-judgment interest as provided by law;
4. For full refund of all purchase costs Plaintiff paid for the Mesh;
5. For compensatory damages in excess of the jurisdictional minimum of this Court;
6. For consequential damages in excess of the jurisdictional minimum of this Court;

7. For punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to impress upon Defendants the seriousness of their conduct and to deter similar conduct in the future;
8. For attorneys' fees, expenses, and costs of this action; and
9. For such further relief as this Court deems necessary, just, and proper.

**DEMAND FOR JURY TRIAL**

Plaintiff demands a trial by jury as to all issues.

BY:



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Dated: October 6, 2017